

A SURVEY OF ATTITUDES AND PRACTICES OF ADULTS WITH SEVERE
FOOD ALLERGIES

A Thesis

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ABSTRACT

Food allergy is a growing problem that affects approximately 12 million people in the United States. Since there is no cure for food allergy, the only way for a food allergic person to prevent an allergic reaction is to avoid the offending food(s). As such, proper education and training of people with food allergy, as well as physicians and the health care community, food service operators and the general public is greatly needed. The purpose of this study was to interview adults, 18 years or older, who have life threatening food allergies and to identify motivators and barriers to safe food selections, as well as barriers to implementation of emergency action plans in case of accidental ingestion of allergenic food(s). Information gathered from this project will be used to design education and training materials for adults with severe food allergies, physicians and food service operators.

Eighty volunteers from New York and New Jersey were interviewed for 60 to 90 minutes using a questionnaire on attitudes and behaviors concerning their food allergies. They were asked about the practices they used to select foods for home preparation and food consumed in other venues, as well as their food practices in restaurants, and preparedness for accidental exposure to food allergens.

Results indicate that although respondents with severe food allergy are relatively confident with the information they have been given by medical personnel, averaging 7.56 on a 10 point scale, (1-helpless, 10-confident), 64 percent mentioned that they have not been adequately informed about how to avoid the foods to which they are allergic, or how to handle a reaction (66%). In addition, confidence in being able to avoid a food allergic reaction outside of the home is significantly lower than in the home. These data, particularly concerning foods to avoid, indicate a lack of awareness that could result in a higher incidence of accidental ingestion of food

allergens. Subjects who carry epinephrine auto injectors are also underinformed about how to use their auto injector as well as the importance of carrying it on a regular basis, and are only moderately confident using it if a potentially severe reaction occurs. In addition, participants are less confident about eating in food service establishments, which could lead to reduced patronage or eating fewer foods.

Study participants made many suggestions about improving confidence and knowledge surrounding their food allergy, including more and better information from medical personnel, and the development of more education materials for food allergy sufferers, as well as educational programs for schools and food service establishments. There was also a desire for alternate forms of epinephrine administration, more training on its use, and smaller, heat-resistant packaging.

The conclusions drawn from this study indicate that there is a deficit of knowledge in people suffering from severe food allergy concerning diagnosis, treatment and management, especially concerning epinephrine auto injectors. There is also a need for greater physician involvement in their food allergic patients' allergy management.

Based on the findings from this study, future research projects should investigate whether supplying the information participants think would improve their confidence and knowledge levels actually has the desired effect. Also, participants emphasized the need for additional educational programs for those who come in contact with food allergic individuals. With this in mind, research should be conducted to determine the best methods of implementing these programs and measuring their effectiveness in food service establishments and schools.

BIOGRAPHICAL SKETCH

Rebecca Brynn Taylor was born in Princeton, New Jersey and raised in Wall Township, New Jersey. She received her Bachelor of Science cum laude in Food Science from Cornell University in May 2005. After graduation, Rebecca explored her interest in product development at Kraft Foods, Inc. She then studied Sensory Science at The Ohio State University for a year researching the use of resistant starches as fat replacers in ice cream. In January of 2007 she returned to Cornell to pursue her Master of Science in Food Science focusing on food allergens with a minor in Communication.

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CHAPTER 1

INTRODUCTION

1.1 Research premise

Food allergy has become a growing public health concern in the United States, that currently affects nearly four percent of the population, or more than 12 million Americans (Food Allergy and Anaphylaxis Network (FAAN) 2008; Sampson 2004). The percentage of children affected is higher (6-8%) than adults (1-3.5%), and the number of children under 5 with peanut allergy doubled from 1997 to 2002, demonstrating food allergy is a problem that appears to be increasing (American Academy of Allergy, Asthma and Immunology (AAAAI) 2007a; Kagan 2003; Sicherer and Teuber 2004). This dilemma is not restricted to the United States, and seems to be a rising concern worldwide (Kagan 2003; Sampson 2004).

There are several hypotheses for why food allergies appear to be increasing, including detection bias, exposure to tobacco smoke, immunizations, and the “hygiene hypothesis.” This theory posits that the immune system has become less able to handle challenges because our environments are too clean. The immune system is designed to combat viruses and infections, but the increased presence of antibacterial products and vaccines have reduced the need for the immune system to fight those challenges. Recent studies have shown that children who are raised in rural areas where there are more challenges to the immune system are less likely to develop allergies, which supports that concept (Kalb 2007; Kukkonen and others 2007).

In addition to people with food allergy, and their family and friends, the issue of food allergy impacts many people, from doctors and healthcare professionals to restaurant personnel. Incidence of food allergic reactions results in 30,000 emergency

room visits, making it the leading cause of anaphylactic reactions treated in emergency departments (AAAAI 2008a; Clark and Camargo 2005; FAAN 2008; FAAN 2006a). And, as 47 percent of emergency room visits and fatalities from anaphylaxis originate at restaurants, food service establishments are the location most likely for a reaction to occur (Formanek Jr 2001). Food allergic reactions also cause approximately 2500 hospitalizations and between 150 to 200 deaths annually (AAAAI 2008a; Clark and Camargo 2005; FAAN 2008; FAAN 2006a). Fatal food-allergic reactions are most common in adolescents and young adults (Sampson, Munoz-Furlong, Sicherer 2006; Sicherer and Teuber 2004). There is currently no cure for food allergies, making education of food allergic consumers an invaluable asset to avoiding offending foods and reducing the severity of encounters with allergens (FAAN 2008).

1.2 True food allergy

Although only four percent of the population is affected by food allergy, studies have shown up to 20 percent of the population believes that they or someone in their family has a food allergy (Sicherer and Sampson 2006; Taylor and Hefle 2001). This can be attributed primarily to the confusion concerning the term “food allergy.” Food allergies and other food sensitivities are individualistic adverse reactions to food that the majority of people can eat with no unpleasant side effects, but that can cause life-threatening reactions in others if the immune system is involved (Taylor and Hefle 2001). Food intolerances, toxic reactions or food aversions can cause symptoms that lay persons may attribute incorrectly to food allergy, prompting them to alter their diet as a result (Kagan 2003; Sampson 2004; Sicherer and Sampson 2006). Figure 1 shows the breakdown of adverse food reactions.

One type of adverse food reaction is microbial, which can be either an infection, such as Salmonellosis, when a person ingests an infectious dose of the

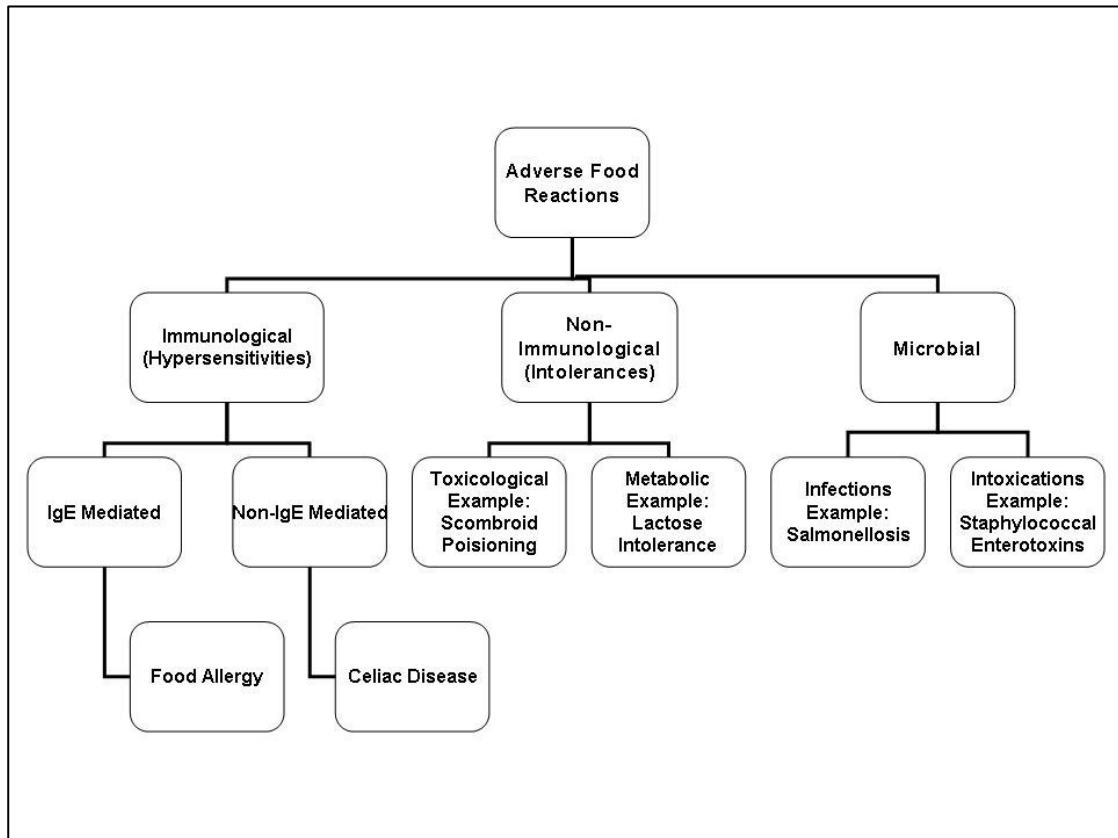


Figure 1: Diagram of adverse food reactions. (USFDA/CFSAN 2006).

bacteria, or an intoxication, such as with Staphylococcal enterotoxins, when a person ingests a food that contains a toxin produced by the bacteria. These food poisoning reactions often show gastrointestinal symptoms such as nausea, vomiting and diarrhea, but can also affect other areas of the body.

Food intolerances are abnormal reactions to foods or food components that do not involve the immune system. The most common symptoms seen with food intolerances are those that affect the gastrointestinal system, but are not caused by an immune reaction. The majority of intolerances are caused by a metabolic disorder in an individual, such as lactose intolerance, which is caused by a deficiency of the enzyme lactase (AAAAI 2007a; Kagan 2003; Sampson 2004; FAAN 2006b).

Other reactions that affect the body, but not the immune system are toxicological or idiosyncratic reactions. Toxicological examples are scombroid

poisoning from fish, or niacin poisoning, or a reaction to pharmacologically active ingredients, such as caffeine (Taylor and Hefle 2001). Food idiosyncrasies are another form of food intolerance in which an adverse reaction occurs without a known mechanism, such as sulfite-induced asthma (Taylor and Hefle 2001). These idiosyncratic reactions are not caused by an immune reaction, but also do not have a clear cause, such as an enzyme deficiency. Food aversions may imitate adverse food reactions as well, but are not reproducible when the patient eats the suspect food in a double-blind placebo-controlled food challenge (Sampson 2004).

True food allergies are heightened responses of the immune system to components of certain foods, most often proteins. Reactions that involve the immune system can be broken into two categories, immunoglobulin E (IgE) mediated and non-IgE mediated. IgE-mediated allergies are the subtype responsible for deaths, hospitalizations and emergency room visits due to anaphylaxis (Sampson 2004; Taylor and Hefle 2001). Celiac disease is the best example of non-IgE mediated reaction, and involves an abnormal immunological response to wheat and related grains. Patients with celiac disease are sensitive to gliadin, a portion of gluten, which causes an inflammatory reaction in the intestine. This leads to flattening of the lining of the small intestine, which interferes with the absorption of nutrients, and can cause chronic diarrhea, weight loss, fatigue or failure to thrive (Sampson 1999a).

1.3 Allergic reaction manifestation

All humans have low levels of IgE antibodies, a class of antibodies that helps the immune system resist disease (Taylor and Hefle 2001). Only some individuals are predisposed to produce antibodies that recognize specific allergens, a trait that is generally inherited (AAAAI 2007a; Formanek Jr 2001; Romeo 2003; Sicherer and Teuber 2004; Taylor and Hefle 2001). The allergens are most often proteins, though

only a small number of proteins in nature are capable of stimulating production of these antibodies. Threshold levels of the allergen can vary by several orders of magnitude depending on the offending food (Taylor and Hefle 2001). Each type of IgE responds only to one type of allergen, which is why people can be allergic only to almonds as opposed to all tree nuts (AAAAI 2007b).

The first step in the mechanism of an allergic reaction is sensitization. Figure 2 depicts cellular sensitization and reaction to an allergen (FDA 2006). During this phase the individual ingests the allergen, which stimulates production of specific IgE antibodies. This can occur at the first ingestion of the food, but that is not always the case. Next, the antibodies attach to mast cells in tissues and basophils in the blood resulting in a sensitized cell (AAAAI 2007b; Formanek Jr 2001; Taylor and Hefle 2001). These mast cells occur in all tissues in the body, but especially in areas that are typically affected by allergic reactions, such as the nose, throat, lungs, skin and gastrointestinal tract (Formanek Jr 2001).

The next time the sensitized cell encounters the allergen it interacts with the IgE antibodies and stimulates the release of allergic response mediators in tissues and blood of the host triggering the symptoms of the allergic reaction. Histamine is one of the primary mediators responsible for symptoms of allergic reactions, though leukotrienes, chemical cytokines, and prostoglandins are also released (AAAAI 2007b; Kalb 2007; Sampson 1999a). The location where the mediators are released determines which symptoms will occur and which organ systems will be affected.

Many factors can influence a systemic manifestation of food allergy and its clinical expression. Genetic disposition and environmental exposure are factors that affect all persons with food allergy in similar ways. Genetic disposition is based on family history of food allergy and determinants of likelihood of being at risk for anaphylactic reactions. The external factors that the immune system has been exposed

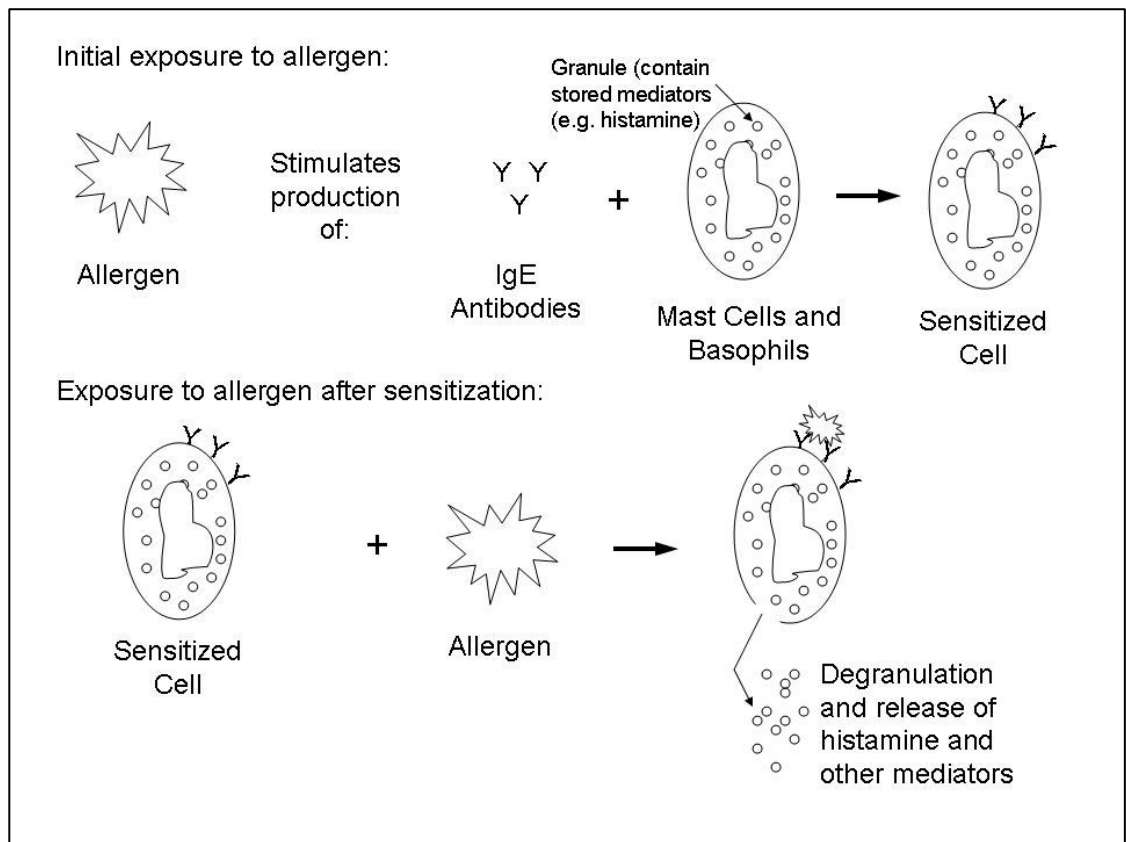


Figure 2: Sensitization and reaction manifestation to an allergen in the body (adapted from Taylor and Hefle 2001)

or sensitized to determines environmental exposure. The route of exposure including whether the food is ingested, inhaled or touched is another factor that influences clinical expression of food allergy. The quantity ingested, protein chemistry, and absorption of the offending food also plays a part in the expression of a food allergic reaction. Protein conformation and breakdown can affect the allergenicity of the suspect food. Also, the contents of the stomach can reduce absorption of the allergen by the body. Target organ reactivity is determined by a patient's other allergic conditions, for example patients with underlying asthma are most at-risk for severe anaphylaxis with respiratory compromise. The last factor that influences systemic

manifestation of an allergic reaction is type, homing and degree of immune response. The type of reaction is determined by whether the IgE antibodies or another aspect of the immune system, such as T-cells or lymphocytes, are activated during a reaction. T-cells can have homing to specific target organs and have a delayed gut reaction, as opposed to the immediate reaction from IgE antibodies (Sicherer 2000).

1.3.1 Symptoms of food allergic reactions

Symptoms of an allergic reaction can happen immediately after ingesting the food, but may take up to 24 hours to occur (FAAN 2006b; Wang and Sampson 2007). The recurrence of symptoms after resolution of the first onset, a biphasic reaction, is also possible. Biphasic reactions may happen in up to 20 percent of anaphylactic reactions and are reported to occur in up to 25 percent of fatal or near-fatal food reactions (Clark and Camargo 2005; FAAN 2006a; Wang and Sampson 2007).

The first presentation of symptoms in the majority of allergic reactions is often itching or tingling of the mouth. Subsequent symptoms of a reaction can range from mild to life threatening. The gastrointestinal, cutaneous or respiratory system can be affected in reactions. Gastrointestinal symptoms include nausea, vomiting, diarrhea, abdominal pain and cramping, and often resemble the symptoms of food borne illness. The cutaneous symptoms most often seen are urticaria (hives), atopic dermatitis (eczema), angioedema (welts) and pruritis (itching). Rhinitis, asthma, congestion, hoarseness, coughing, wheezing and chest tightness may be exhibited by the respiratory system (Taylor and Hefle 2001; Wang and Sampson 2007). The most common symptoms of food allergy are oral itching, swelling of tongue and throat, difficulty breathing, hives, vomiting, abdominal cramps and diarrhea (FAAN 2006b).

1.3.2 Anaphylaxis

A severe allergic reaction, known as anaphylactic shock, has rapid onset and can involve any of the aforementioned symptoms. It can also include symptoms in other systems and may include cardiovascular symptoms, such as tachycardia (rapid beating of the heart), arrhythmia (abnormal heart rate or rhythm), and hypotension (abnormally low blood pressure) or neurologic symptoms, such as anxiety, headache, seizure, loss of consciousness, feeling of “impending doom” (AAAAI 2007c; Clark and Camargo 2005; Wang and Sampson 2007). There is not a universal definition for anaphylaxis, though it is most often identified as a systemic reaction that involves two or more organ systems, including those a distance from the initial entry site of the allergen (AAAAI 2007c; FAAN 2006a). Anaphylactic reactions can lead to death as the swelling of the airway is often accompanied by a rapid drop in blood pressure, which can occur within minutes. The most dangerous symptoms are low blood pressure, breathing difficulties, shock and loss of consciousness, all of which can be fatal (AAAAI 2007c). The most common indications of a severe allergic reaction include any oral or throat swelling which could block the airway.

1.4 Big eight allergens

In the United States 90 percent of food allergies are to eight foods, known as the “Big Eight.” These foods are cow’s milk, hen’s eggs, wheat, soy, peanuts, tree nuts (almonds, walnuts, pecans, cashews, etc), fish, and crustacean shellfish (shrimp, crab, lobster, crayfish) (FAAN 2008; Taylor and Hefle 2001; United States Food and Drug Administration 2006). The first five (milk, eggs, wheat, soy and peanuts), are responsible for most food allergies in children, and 85 percent of allergies to the first four may be outgrown by the age of five. Allergies to the second four (peanuts, tree nuts, fish and shellfish) are more common in adults and tend to be lifelong after onset

(Kagan 2003; Sampson 2004; Sicherer and Teuber 2004; Sicherer and Sampson 2006). Among adults in the U.S., peanuts are thought to be the most common allergenic food, and allergy to peanuts appears to be more common in North America than in other parts of the world. In other countries, allergic responses occur frequently to different foods, such as celery in some European countries, buckwheat in Southeast Asia, and sesame seeds in Middle Eastern countries, possibly due to the popularity of tahini, a paste made from sesame seeds (Taylor and Hefle 2001).

Peanuts, tree nuts, fish and shellfish are responsible for the majority of severe reactions across all ages in the United States (Clark and Camargo 2005; Simonte and others 2003; Wang and Sampson 2007). Estimates for Americans with allergies to these foods were determined by random telephone surveys. Between 3.3 and 3.6 million people self-report an allergy to either peanuts or tree nuts (Andrews and Banks 2005). Seafood allergy is self-reported by 6.5 to 6.9 million people, with shellfish allergy reported by 1-in-50 Americans and a fish allergy by 1-in-250 (Sicherer, Munoz-Furlong, Sampson 2004). Peanut allergy is the most common cause of severe and fatal food-allergic reactions, and combined with reactions caused by tree nuts accounts for 90 percent of food allergen fatalities (Ewan and Clark 2005).

1.5 Diagnosing a food allergy

Because there is a wide range of symptoms that can be attributed to IgE-mediated food allergy, and because there are a number of other causes for these symptoms, it can sometimes be difficult to diagnose. An allergist or immunologist is the best qualified professional to diagnose an allergy, which is done by a careful evaluation of the patient's history and proof of the food-specific IgE mechanism (Kagan 2003; Sampson 2004; Sicherer and Sampson 2006; Taylor and Hefle 2001). Over diagnosis or self-diagnosis can be erroneous and lead to implication and

avoidance of additional or incorrect foods possibly resulting in malnutrition or eating disorders, while underdiagnosis can leave the patient suffering unnecessarily (Sampson 1999b). The medical history should help establish the suspect foods, the time for symptoms to develop, whether ingestion of the food has elicited similar symptoms on other occasions, whether other factors, such as exercise, are necessary to produce the symptoms, and when the most recent reaction occurred (Sampson 1999b; Sicherer and Sampson 2006). In addition to a complete medical history, four detection methods are employed to determine suspect foods: food diaries and/or elimination diets, skin prick tests, in vitro assays, and double-blind, placebo-controlled food challenges (DBPCFCs).

Food diaries and elimination diets are non-invasive methods of identification. The patient keeps a chronological record of all foods eaten over a certain period of time and any symptoms that develop. These diaries are likely to provide a less biased recall of foods eaten than a remembered food history and can reveal unknown sources of contamination or hidden food allergens. Through analysis of a food diary, an experienced allergist can often ascertain suspect foods. This method of detection is useful in the evaluation of chronic disorders in relation to food allergies such as atopic dermatitis (Sampson 1999b; Taylor and Hefle 2001).

Allergy skin tests are a second way to determine which foods are triggering symptoms. A small amount of liquid extract made from the food is put on the skin and a needle is passed through the liquid to the top layer of skin. If the patient develops a wheal, a small raised bump or hive, within 20 minutes, a possible allergy is indicated (AAAAI 2007a). Skin prick tests can be used on patients of all ages and are rapid and inexpensive. When the tests are negative, food allergies can be excluded with a 95 percent or higher negative predictive value. Positive predictions, however, are less than 50 percent accurate when compared with DBPCFCs, and therefore

dependent on pretest probability as determined by review of the patient's history by a physician (Kagan 2003; Sampson 2004; Sicherer and Teuber 2004; Sicherer and Sampson 2006).

In vitro assays, such as the radioallergosorbent test (RAST), identify the presence of food-specific IgE antibodies in the blood serum (Taylor and Hefle 2001). Higher concentrations of the antibodies correlate with an increasing probability of an allergic reaction. When the patient's levels exceed published predictive values it is more than 95 percent likely he or she will experience a clinical reaction, although in 10 to 25 percent of clinical reactions undetectable serum food-specific IgE levels may be responsible (Sicherer and Teuber 2004; Sicherer and Sampson 2006)

The gold standard for documenting adverse reactions to food and diagnosing food allergy is the DBPCFC (Kagan 2003; Sicherer and Teuber 2004; Sicherer and Sampson 2006; Taylor and Hefle 2001). In this method incremental quantities of the suspect food are administered in a blinded, controlled setting. The patient is supervised, as anaphylaxis can occur, and symptoms are observed (Kagan 2003; Sicherer and Teuber 2004). Open or single-blind oral food challenges can also be useful in screening for reactions.

1.6 Treating and managing a severe food allergy

Currently, the principal therapy for treating food allergy is to eliminate the offending foods from the diet (AAAAI 2007a; Kagan 2003; Sampson 2004; Sicherer and Teuber 2004; Taylor and Hefle 2001). There is presently no cure for food allergy, however, a number of immunotherapy options are being explored. Until these treatments can be evaluated and safely and carefully implemented, monitoring foods chosen for consumption is the only available option for food allergy sufferers. Therefore, patients need to be properly educated about reading labels on commercial

food products and inquiring about ingredients when dining outside the home, as elimination of the allergen is often a challenging task (Formanek Jr 2001). Individuals with severe food allergy should also be encouraged to obtain medical alert bracelets, taught to recognize symptoms and instructed on the use of self-injectable epinephrine (AAAAI 2007a; AAAAI 2007c). Since it is possible to outgrow an allergy over time, re-evaluation of the patient's situation may be appropriate depending on the allergen and the patient history (Sampson 1999b; Sicherer and Teuber 2004).

1.6.1 Current immunotherapy research

In a minority of patients who experience peanut-induced anaphylaxis, treatment using anti-IgE antibodies has demonstrated that they have been able to tolerate larger quantities of peanuts, but the adverse reaction rates are unacceptable (Sampson 2004). Under medical supervision, egg oral immunotherapy has also been attempted in children who are allergic to eggs and have not experienced anaphylaxis. First the patients were put through rush phase where subjects were exposed to a single dose of 0.1 milligram (mg) of powdered egg white, and then subsequent approximately doubled doses every 30 minutes until the highest tolerated single dose was determined. The build-up phase followed where subjects had daily home dosing based on the previously determined highest tolerated dose, between 25 and 200 mg. As long as subjects tolerated current doses they increased their dose by 25 mg every 2 weeks until reaching 150 mg, and then increased by 50 mg every 2 weeks until the maintenance dose of 300 mg was reached. Patients then ingested an egg protein dose of 300 mg daily for 24 months, with the expectation that the dose would protect subjects from accidental ingestion and induce oral tolerance to egg. This treatment may be useful in preventing reactions due to accidental ingestion, though success has not been demonstrated in anaphylactic patients (Buchanan and others 2007).

Researchers in Finland have attempted to combat the hygiene hypothesis for increase in allergic diseases through dietary supplementation of pregnant women and their children after birth. Live commensal probiotic bacteria were supplied to the women and children to promote early immune system maturation. In a randomized study, 1223 pregnant women carrying children at increased risk for allergy in Helsinki were supplied with either a probiotic preparation or a placebo for two to four weeks before delivery and their infants were given the same probiotics plus galacto-oligosaccharides or placebo for six months. At the end of 2 years, children were evaluated for the incidence of allergic diseases. This treatment showed no effect on food allergy, but did reduce IgE-associated atopic diseases such as eczema (Kukkonen and others 2007).

Other alternative approaches to addressing food allergy treatment are also being investigated, and include a project where the use of a traditional Chinese herbal medicine formula in mice exposed to peanut allergens was studied. Project results demonstrated a protective effect in the mice for almost 25 percent of their lifespans (Wang and Sampson 2007). Presently no immunotherapy treatments have been proven to protect patients at all levels of sensitivity to food allergens, nor have any been shown to be a lifelong cure. Consequently, antihistamines, steroids and epinephrine are the only medicinal aids available at this time.

1.6.2 Epinephrine and other medications

In the case of an allergic reaction there are several medicinal options to choose from: antihistamines, corticosteroids, or epinephrine. Antihistamines are frequently employed for less severe reactions or when a small amount of the allergen has been ingested. They have been shown to be effective in the treatment of cutaneous symptoms, but less so for the respiratory or gastrointestinal systems

(Sampson 2004; Sicherer and Sampson 2006; Wang and Sampson 2007). Steroids are commonly successful in treating chronic IgE-mediated allergies, but the side effects are frequently deemed objectionable by patients (Sampson 2004).

The principal treatment for patients with life-threatening food allergies is epinephrine and early administration is critical (Taylor and Hefle 2001). It is recommended that people who have a history of anaphylaxis, have allergies to foods that commonly cause severe reactions (peanuts, tree nuts, fish and crustacean shellfish), have underlying asthma, or have a family history of severe food allergy be prescribed epinephrine. Only a physician can prescribe the use of epinephrine. Auto injectors should only be used according to a physician's instructions, at the onset of respiratory or cardiovascular symptoms, or at the first sign of a reaction in patients with a history of anaphylaxis (AAAAI 2007c). More severe or deadly reactions may occur if treatment is delayed in patients who have been prescribed epinephrine (Gold and Sainsbury 2000; Sampson 2004; Sampson, Munoz-Furlong, Sicherer 2006; Simons, Gu, Simons 2000). Although symptoms may be resolved early due to treatment, once epinephrine has been administered it is then important to contact emergency services for observation and to prevent a biphasic reaction, or reoccurrence of severe allergic symptoms (Sicherer and Sampson 2006; Simons 2004).

Epinephrine is used to treat anaphylaxis because it helps to reverse hypotension by increasing blood flow to the body's core and to alleviate bronchospasm. It has also been shown to block mediator release and to reverse the effect that histamine, leukotrienes and prostaglandins have on organ systems (Gold and Sainsbury 2000; Simons 2004). Administration is significantly more effective when done as an intramuscular rather than subcutaneous injection, and when administered in the upper thigh, the vastus lateralis muscle, due to its size and amount of blood supply, rather than in the arm (Simons 2004; Wang and Sampson 2007).

Adverse reactions to epinephrine include palpitations, tachycardia, anxiety, headache, tremor, hypertension, and acute pulmonary edema (Simons 2004). Self-injectable epinephrine has been shown to temporarily reverse the progression of an allergic reaction, providing time for the patient to obtain emergency treatment from medical personnel (AAAAI 2007c).

There are currently two brands of prescription epinephrine dispensers on the market: the EpiPen[®] and the Twinject[®] which are shown in Figure 3. Both types are auto injectors with concealed needles that dispense epinephrine in fixed doses of either 0.15 or 0.30mg (AAAAI 2008b; Kagan 2003). The Twinject[®] contains two doses of



Figure 3: EpiPen and Twinject epinephrine auto injectors

epinephrine per auto injector with the second being administered by pushing the plunger of a syringe (Verus Pharmaceuticals 2008). Instructions for use are included in the exterior packaging of the auto injector as well as abbreviated instructions on the auto injector itself (Dey 2008; Verus Pharmaceuticals 2008).

There are limitations to the effectiveness of self-injectable epinephrine depending on the rapidness of onset of the reaction and the way the epinephrine is administered. Mistakes can be common in the use of auto injectors, so patients who carry them should be instructed properly about when to use the device, how to use it, and when to replace expired prescriptions (Wang and Sampson 2007). Prior practical demonstration has been associated with a four- to five-fold greater chance of using an epinephrine auto injector correctly (Arkwright and Farragher 2006). Underuse, delay of use, failure to inject, inappropriate dosage, or inappropriate route of administration have all been implicated in deaths due to anaphylaxis where self-injectable epinephrine was available (Gold and Sainsbury 2000; Sampson 2004; Sampson, Munoz-Furlong, Sicherer 2006; Simons, Gu, Simons 2000). Recognition of symptoms of anaphylaxis is frequently deficient in severely food allergic patients, but it has been shown that empowerment of patients correlates with increased comfort in the use of epinephrine auto injectors, while an increase in knowledge alone does not (Kapoor and others 2004; Kim, Sinacore, Pongracic 2005). Additionally, patients must pay attention to the expiration date on their prescription, as out-of-date auto injectors have been shown to have significant reduction in bioavailable epinephrine, which correlates inversely with the amount of time past its expiration date (Simons, Gu, Simons 2000).

1.6.3 Allergen identification

One of the most important sources of information for people with food allergies is the ingredient list provided on packaged foods (Taylor and Hefle 2006). Correct food labeling can be helpful for food allergy sufferers in recognizing the presence of substances they need to avoid, as reading labels is the only way to determine dangerous allergens in packaged food (Formanek Jr 2001). As of January 2001, the US Food and Drug Administration (FDA) reported that 25 percent of products contained undeclared allergenic ingredients, most often from cross-contamination. Cross-contamination happens unintentionally, most often through poor cleaning and cross contact processing schedules or improper cleaning of utensils. During the FDA's fiscal years 1999 to 2004, there were 462 food recalls due to the presence of undeclared allergens in a food. Four particular undeclared allergens, egg, milk, peanut, and tree nut ingredients, were most frequently associated with recalls. As food manufacturers may substitute ingredients without changing the exterior packaging, it is important for people with food allergies to reevaluate the safety of the foods they eat on a regular basis (Formanek Jr 2001).

1.6.3.1 Food Allergen Labeling and Consumer Protection Act

In January 2006, the US Congress enacted a new labeling law, the Food Allergen Labeling and Consumer Protection Act (FALCPA). Foods packaged after that date are required to identify the sources of ingredients derived from commonly allergenic sources (the Big Eight food allergens) in "plain English language" (Taylor and Hefle 2006; United States Food and Drug Administration 2006). For example, casein and whey must now be identified as possible milk allergens and semolina must be identified as wheat. These regulations apply to all packaged foods sold in the U.S. that are regulated under the Federal Food, Drug, & Cosmetic Act, including both

domestically manufactured and imported foods (United States Food and Drug Administration 2006). This act also requires the FDA to submit a report to Congress suggesting ways to reduce or eliminate cross contact during harvesting, transportation, manufacturing, processing, or storage (Bren 2006).

This law was enacted to address identified difficulties in labeling foods. Previously certain ingredients could be identified collectively, such as spices or natural and artificial flavors (Joshi, Mofidi, Sicherer 2002; Taylor and Hefle 2006). The source of an ingredient did not need to be declared, so that could cause confusion. For example, lecithin can be derived from several sources such as soy or egg and may be present in amounts lower than threshold levels for those allergens (Taylor and Hefle 2006). In addition, common names for food allergens were not required, so a layperson might not be able to identify casein, lactoglobulin or lactalbumin as milk proteins. Many consumers may not have been aware that nondairy foods may contain milk byproducts (Formanek Jr 2001).

The presence of allergenic foods must now be stated and can be declared in several ways. One way is to simply identify the allergenic food in the ingredient list, for example wheat starch or soy lecithin. Another way is to put the allergenic food in parentheses following the ingredient: starch (wheat) or lecithin (soy). A third method is to put a “contains” statement directly underneath the ingredient list, for example “this product contains: wheat, soy.” This method, however, can cause confusion as it does not specify which ingredient is derived from which source (Taylor and Hefle 2006).

There are some concerns with the amount of information that will now be available to consumers about food allergens. Evidence documenting the allergenicity of ingredients that contain very low amounts of the allergenic proteins is lacking, but labeling of these ingredients is still required (Formanek Jr 2001; Taylor and Hefle

2006). The identification of allergenic sources for ingredients that have been demonstrated to be safe for the majority of allergic subjects to ingest, such as lactose in milk allergic infants or fish gelatin in fish allergic subjects, could lead to serious restriction of diets of allergic consumers (Taylor and Hefle 2006).

1.7 Situations of concern

Allergic reactions can be caused not only by the ingestion of the allergen, but also in sensitive individuals by physical contact with a suspect food or a surface on which the food has been placed (Simonte and others 2003). Proteins in the vapor or steam from cooking allergenic foods or particulates from opening a package containing the food have been shown to elicit asthmatic reactions and anaphylaxis in certain individuals as well (Sampson 2004; Sicherer and Teuber 2004). There has even been evidence of severe reactions from kissing a person who has recently ingested the allergen (Simonte and others 2003). Anaphylaxis can also occur in individuals if they exercise within two to four hours after ingesting a food. This is referred to as exercise induced anaphylaxis (Sampson 2004; Sicherer and Teuber 2004).

1.8 Restaurants and food allergy

Despite the recent legislation for packaged foods, restaurants are not required to list ingredients on their menus. Since nearly half of emergency room visits for allergic reactions to food are caused by ingestion of the allergen at a restaurant, effective communication between food allergic customers and food service personnel is vital. Failure of communication between these two parties is a frequent cause of errors that result in allergic reactions (Furlong, DeSimone, Sicherer 2001).

Hospitality educators have indicated that the topic of food allergies is only briefly discussed in classes, if it is discussed at all, and most food management textbooks that do address food allergies do so in a very limited manner (Mandabach, Bloomquist, Rande, VanLeeuwen 2002). In addition, according to a recent study by Mandabach, Ellsworth, VanLeeuwen, Blanch, and Waters (2005), only one third of restaurants surveyed (810 restaurants in a local chapter of the restaurant association) included food allergies in their employee-training programs, leading to even less awareness by entry level employees. Restaurant managers, people directly in contact with allergenic foods and allergic consumers, are also not as informed as they should be. Eighty-one percent said they were aware of food allergy, though only 57 percent of that number could define what a food allergy was. In addition, 28 percent of respondents did not feel incorporating food allergy precautions was important in restaurant food safety education for their staff.

Food service personnel demonstrate a lack of correct information concerning food allergy. As Mandabach and others (2005) found, although managers claim to be aware of food allergy, less than half can properly define it. When asked for examples of causes of allergic reactions respondents mentioned bad hamburger, raw chicken and bad food control as reasons for food allergy incidences. This is because they frequently confuse food allergies with food safety issues, such as food poisoning and food intolerances. While 94 percent of managers could answer questions correctly about food poisoning, the number drops to 81 percent for food allergy and 50 percent for food intolerances. Food servers are also frequently uninformed and may falsely reassure an allergic patron an item is allergy free because they are unaware of all the ingredients included in a recipe. That is not the only problem; more than 20 percent of servers believe it is alright to remove, or pick off, an allergen when an item is made incorrectly, as they are unaware that a food in contact with the allergen is able to cause

a reaction as well. The offending allergen may also be a hidden or “secret” ingredient in a complex menu item (Furlong, DeSimone, Sicherer 2001).

Food service personnel do not always bear sole responsibility, however, every time a reaction occurs in an establishment. In a study of peanut and tree nut allergic reactions in restaurants and other food establishments, only 45 percent of patrons gave prior notification about the allergy to the server. In addition, some of these reactions were due to ingestion of food not intended for them (Furlong, DeSimone, Sicherer 2001). The National Restaurant Association in collaboration with the Food Allergy and Anaphylaxis Network (FAAN) have created a dining card that can be personalized, printed and shown to food service personnel, which will alert servers that the consumer has a severe medical condition (FAAN 2006b). The card can be accessed at www.foodallergybuddy.com (Lempert 2007).

As food allergy becomes a more prevalent problem, it is important that restaurants begin to take a proactive approach to this issue. Many publications intended for food service personnel make recommendations for increased awareness of food allergy both to protect the consumer and to prevent liability issues. Suggestions have included education of employees about what food allergy is, its difference from a food preference, and its severity; keeping track of utensils and cooking methods used in the preparation of allergenic foods; establishing written guidelines on how to handle common allergenic foods; and asking guests about potential allergies before they order (Adshead 2006; Barth 2004; Duecy 2004; Harmer 2005; Modlin and Krummert 2005; Morgan-Harris 2004; Tellem 2005). Currently many food chains have only a poster on the wall to designate ingredient lists, though more proactive restaurants verify that their ingredient suppliers do not have cross-contamination problems, or use different color tickets in the kitchen to designate guests with a food allergy (Duecy 2004).

1.9 Communicating food allergy

Obtaining scientifically sound and accurate information on food allergies from physicians, nurses and other credible sources is an important asset for any food allergic individual. Without proper information, patients may not be aware of the symptoms of an allergic reaction, know how to treat a severe reaction, or be able to avoid the foods to which they are allergic without becoming malnourished (Taylor and Hefle 2001). Families of children with food allergy have been shown to have deficiencies in their knowledge of avoiding allergens and managing reactions (Kapoor and others 2004). In an online study of 174 adolescents and young adults to determine risk-taking and coping strategies of adolescents with food allergy, 68 percent believed additional education would make living with food allergy easier, indicating that education of people with food allergy and their peers may reduce risk taking and its consequences (Sampson, Munoz-Furlong, Sicherer 2006).

1.9.1 Clinician intervention

A study of physicians by Zeiger and Schatz (2000) suggested that physicians take a greater responsibility for patients with anaphylaxis by providing education about risk, discussing long-term risk reduction strategies, supplying accurate information about anaphylaxis and developing an emergency action plan to implement in case of ingestion. Although physicians are responsible for diagnosis, many general practitioners do not use guidelines for food allergy treatment supplied by allergists. Only 35 percent of general practitioners use any of these treatment guidelines (Zeiger and Schatz 2000). This is despite the fact that a recent study of parental knowledge, and the rate of succeeding allergic reactions after education, has shown that a single visit to a clinic can improve the family's ability to manage a reaction and reduce the number of subsequent reactions. In a study conducted in a pediatric allergy clinic in

London, England, with the parents of 62 food allergic children, their knowledge of food allergies was assessed by questionnaire before seeing a pediatric allergist, clinical nurse specialist and dietician, and reassessed three months after the visit. After one visit to the clinic, there was significant improvement in parental knowledge of allergen avoidance (26.9%, $p < 0.001$), managing allergic reactions (185.4%, $p < 0.0001$) and EpiPen® usage (83.3%, $p < 0.001$). Also, having an emergency plan of action supplied by a physician reduces the frequency and severity of later reactions (Kapoor and others 2004).

Non-adherence to physician recommendations by patients can also occur, reducing the effectiveness of education. Barriers to following prescribed plans of action attributed to treatment can include: benefits of the treatment not being immediately apparent to the patient; expense or side effects of the medication; complexity or lack of clarity in instructions. Clinician-related barriers include apparent lack of interest of the physician, difficulty in scheduling appointments, and contradictory advice. Lack of understanding, severity of reaction, lack of faith in the physician, as well as psychological or family problems are barriers ascribed to the patient. Suggestions for increasing adherence are to educate patients and their families, by providing sufficient information about the disease and treatment; to discuss the treatment in detail and listen to the patient's concerns; to establish treatment goals with the patient by tailoring their regimen to their specific allergy; to increase availability of appointments; and to motivate patients by being more resourceful in alternate approaches to clarify severity and importance of treatment (Bender 2002).

1.10 Societal impacts of food allergy

Food allergies can have a substantial influence on people affected by them, both in quality of life and financial costs, and on society in general. Direct costs may include: physician visits, emergency services utilization, medications, hospitalizations, diagnostic testing, and informational materials (Miles and others 2005; van Putten and others 2006). These costs can be weighed against each other, such as the cost of immunotherapy versus emergency care in the long term, though there is no guarantee that money spent initially for prevention will be more monetarily advantageous compared with the costs associated with possible required emergency services (Miles and others 2005). There are also indirect costs to society, such as lost productivity due to sick days or restricted activity for those with food allergy, loss of promotional opportunities due to care of a family member with food allergy, or expenses of changes in regulation in the food industry (Miles and others 2005; van Putten and others 2006). Loss of productivity affects society as a whole as it affects both individuals and their employers. Quality of life costs are hard to quantify, but can include health, financial security, standard of living, family and friends, or spiritual contentment (Miles and others 2005). Parents of children with food allergy have been shown to have low scores on quality of life measures in regards to family activities, general health perception and parental emotional effect (Cohen and others 2004). Other monetary impacts on society are expenses associated with food safety regulation, increased food development and production costs, and a potential loss of markets (Miles and others 2005).

1.11 Research Interests

One area of continuing concern is how severely food allergic individuals manage their life-threatening food allergies. The purpose of this study was to

determine the current knowledge of people living with severe food allergy, and to identify motivators and barriers to following prescribed information from medical personnel. In addition, it sought to ascertain what type of information would be most beneficial for participants, what sort of sources they would like to receive it from, and who else they believed needed additional education. The principle behind this study was that those with food allergy are the primary stakeholders in future education, and as such would be the best resource in determining the specific content needed in newly developed educational materials and their delivery.

CHAPTER 2

METHODS

2.1 Research Design

This research study is part of a large, collaborative project undertaken with colleagues at the University of California, Davis and is similar to an earlier study conducted by Phillippo and Bruhn in California (2007). Funding for this project, entitled “A Multifaceted Food Allergy Education Program,” was made possible through a grant (Project # 2003-51110-01728) from the United States Department of Agriculture, Cooperative State Research, Education and Extension Service, National Integrated Food Safety Initiative. Other project collaborators were researchers at Mt. Sinai School of Medicine, the Center for Food Safety and Applied Nutrition at the US Food and Drug Administration (FDA) and the Food Allergy & Anaphylaxis Network (FAAN). FAAN is an organization founded to raise public awareness, to provide advocacy and education, and to advance research on behalf of all those affected by food allergies and anaphylaxis.

The purpose of this segment of the project was to determine motivators and barriers to safe food selection, and to identify barriers to implementation of emergency action plans in case of accidental ingestion in adults with life-threatening food allergies who live in New York and New Jersey. It examined the perceptions of the information and education people with food allergy have received and its relationship with their ability to manage their food allergies successfully. Findings from all parts of the project will be used to design educational materials for adults with severe food allergies, develop materials for physicians that detail appropriate recommendations for food allergic patients, and deliver an educational program for food service workers on appropriate precautions to take for customers with severe food allergies.

2.2 Subject Recruitment

Participants in this study were required to be over the age of 18 and have a self-reported severe food allergy that had resulted in emergency room care or an EpiPen® prescription. Subjects were recruited through advertisements in classrooms, through press releases and newspapers articles, through listservs and also from information presented in radio and television interviews. Subjects were initially recruited on the Cornell University campus through faculty who teach large classes. Material about the study was provided to faculty as lecture slides and handouts. These materials provided information about the study, participant requirements and investigator contact information. The same information was sent out through appropriate campus listservs. WVBR, a local radio station operated by Cornell University students, interviewed Dr. Robert Gravani about food allergy and provided information about the study to listeners. A television interview about food allergy and the study was conducted with Dr. Gravani and Rebecca Taylor on the program “Food for Thought” aired on WCNY, a PBS affiliate in Syracuse. Study participants were also recruited from selected cities in New York with the assistance of the Cornell News Service. The News Service developed and issued a statewide press release with details about the study and made direct contact with major newspapers in larger cities. As a result, newspaper articles on food allergies were run in many cities throughout New York state. FAAN also assisted in recruitment by sending out information about the study to their members through listservs in New York and New Jersey.

In total, 147 people responded to recruitment materials, and 111 were pre-qualified after a phone screening and were mailed the first questionnaire (Appendix A). Of the individuals who received the mailer questionnaire, a total of 82 participants contacted the researchers after completing the mailer questionnaire and were interviewed for the study. After analysis, of those 82, 80 fit the parameters of the study

and were included in the data analysis. All subjects gave informed consent, in accordance with the approval of methods by Cornell University Institutional Review Board for Human Participants (Appendix B). The identity of the participants was kept strictly confidential and responses were coded to assure their anonymity. Subjects were compensated for their time and received twenty-five dollars in cash at the completion of the oral interview. Participants will also be sent results of the study as well as educational materials on food allergy developed from the study and from other selected resources.

2.3 Materials

The two questionnaires used in this study were developed by researchers at the University of California, Davis and reviewed by project collaborators. The first questionnaire was mailed to participants to introduce the type of questions to be asked in the interview and reduce total time of the subsequent interview. This questionnaire will be referred to as the mailer questionnaire. The second questionnaire (Appendix C) was developed for the oral interview and will be referred to as the interview questionnaire. Additional materials used during the interview can be found in Appendix D. All oral interviews were recorded on an Olympus DS-30 digital voice recorder and transferred to a computer.

2.4 Methodology

The mailer questionnaire was sent to participants after initial determination of eligibility in the study. Subjects were asked to complete the mailer questionnaire and then contact the interviewers to schedule an interview. The mailer questionnaire took about 15 to 20 minutes to complete. The interview was then scheduled in a location convenient to the participant. The oral interviews took approximately one hour and

were conducted by Rebecca Taylor. All interviews were recorded to ensure accuracy of reporting and backed up on CD.

Responses were analyzed by percentage by dividing the number of responses given by the total number of participants who were asked the question. No responses (NR) and the number of responses given as “don’t remember” (DR) or “not sure” (NS) were subtracted. T-tests and Mann-Whitney nonparametric tests were performed on selected questions to determine statistical relationships. Answers recorded as “no” were coded with a 0, answers recorded as “yes” were coded with a 1. For Mann-Whitney tests on how often the epinephrine auto injector was carried “never carried” was coded 0, “sometimes” and “only at certain times” were coded with a 1, and “always carry” was coded as 2. Additionally, the data obtained by colleagues who conducted the study in California was compared with data obtained in this study.

CHAPTER 3

RESULTS

3.1 Demographic Information

A total of 19 males and 61 females ranging in age from 18 to 78 were interviewed. Most participants identified themselves as Caucasian (68). In addition, there were two Asians, two African-Americans, one person of Hispanic origin and seven participants who identified themselves as multi-ethnic. Food allergies were noticed in almost half of the participants (46%) by the age of ten, with another 21 percent developing allergies by age 20, and one person was diagnosed in her 70s (Figure 4). People who experienced additional allergies developed them across all ages with the more than half (55%) occurring under the age of 20, though 20 percent were developed during their 40s and 50s. Approximately half (52%) of respondents had a family history of food allergy.

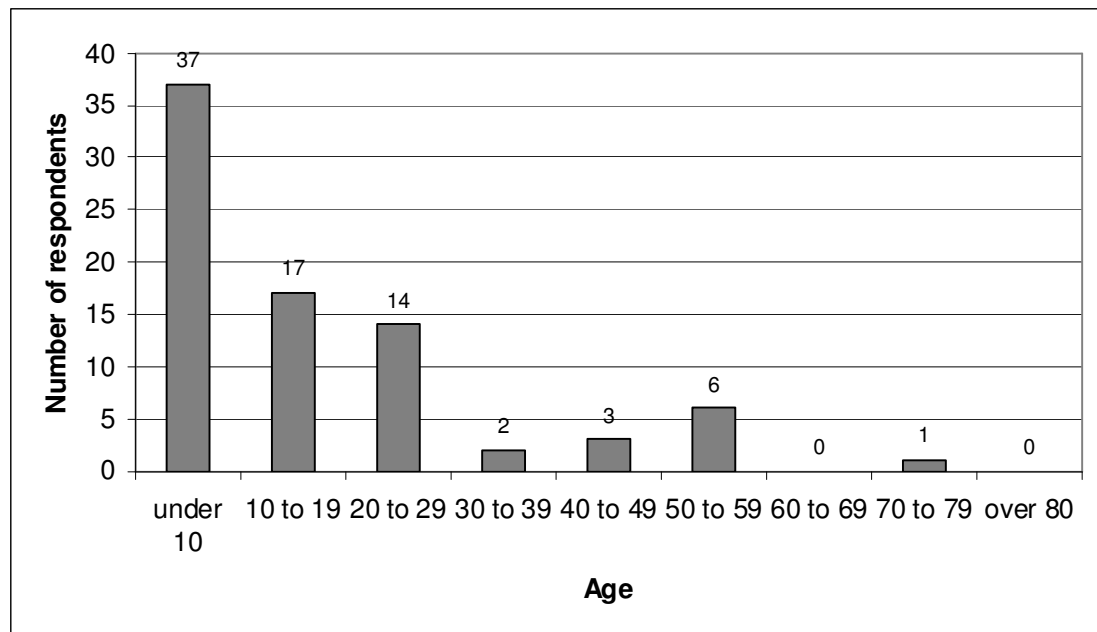


Figure 4: Frequency of age when food allergy was first detected (n = 80)

Subjects reported having a history of asthma (55%), insect sting allergy (20%), red itchy skin (50%), hay fever (81%), and drug allergies (45%), and twenty-nine percent had received allergy shots. An allergist was consulted by 84 percent of participants for at least one allergy problem. Medical alert bracelets were worn by 16 percent, although bracelets had been recommended to 31 percent (n=78). Nearly a third of participants (29%, n=78, 2 NR) are members of FAAN.

3.2 Foods

Shellfish (29%) was the most common reported food associated with a first allergic reaction followed by tree nuts (24%) and peanuts (16%) (Figure 5).

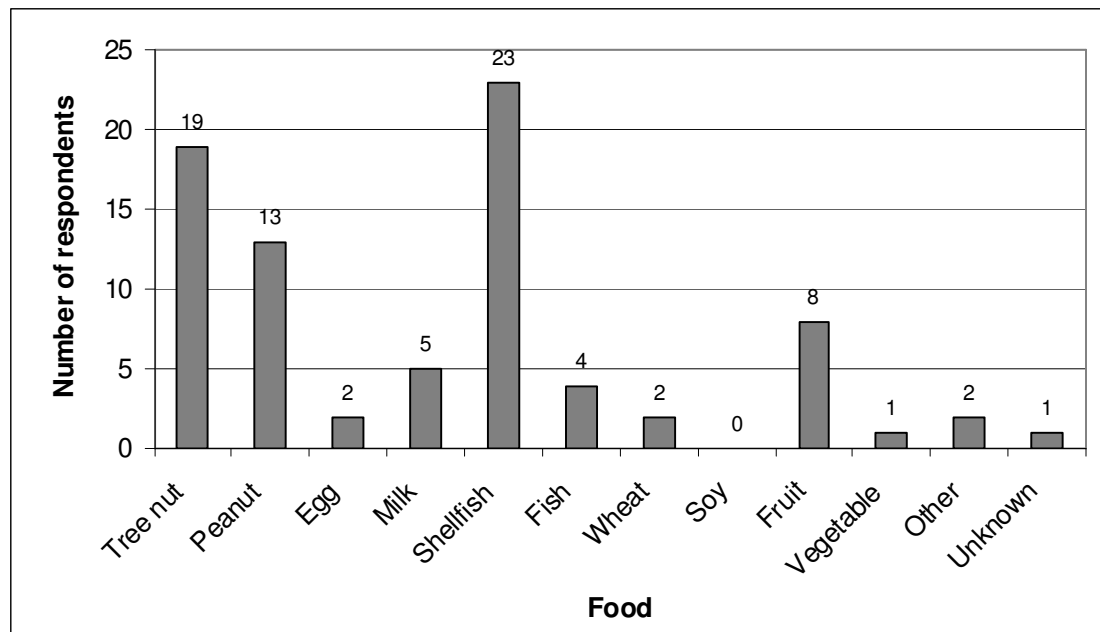


Figure 5: Frequency of food allergen reported for first reaction to a food (n = 80)

More than three quarters (78%) of the volunteers are allergic to more than one food. Of all allergies reported, including participants with multiple allergies, tree nuts and shellfish were most often named as causing a reaction followed by fruits, peanuts and

milk. In 34 percent of allergen exposure, respondents had a reaction the first time they ingested the food, while the remaining 66 percent had previously tolerated the food that caused the reaction.

3.3 Triggers

Most participants' (84%) reactions were not made more severe by whether the allergen was raw or cooked, but for 13 people it was a factor. In eleven of those affected individuals, the raw food caused a more severe reaction. Approximately half of respondents (51%) have had a reaction by merely touching the food. Almost all participants (91%) have heard that they can have a reaction by kissing someone who had ingested the allergen or breathing in particles, and the majority (90%) were self-taught about these possible causes of a reaction through their own research or by seeing it in the media. Only 12 individuals have had an allergic reaction by kissing someone, while 29 have had a reaction by breathing in cooking vapors and 21 have had a reaction by inhaling particles.

3.4 Symptoms

Participants reported experiencing a variety of symptoms during the worst food allergic reaction they could remember. The most common symptoms recounted by study volunteers were throat swelling (82%), facial swelling (37%), hives (36%), itching (33%), shortness of breath (28%), redness of skin or flushing (22%), and nausea (19%) (Table 1). In 89 percent of subjects, onset of symptoms began in under 30 minutes, with 62 percent of these had symptoms that started in less than five minutes after ingestion of the offending food (Figure 6).

Table 1: Symptoms described during the worst reaction participants could remember clearly* (n = 78, DR = 2)

Symptom	N	Percent
Throat swelling	64	82.1
Swelling of face	29	37.1
Hives	28	35.9
Itching	26	33.3
Shortness of breath	22	28.2
Redness of skin, flushing	17	21.8
Nausea	15	19.2
Swelling of other areas of the body	13	16.7
Wheezing	8	10.3
Sense of doom	5	6.4
Vomiting	5	6.4
Light-headedness, dizziness	5	6.4
Burning/Hot	5	6.4
Coughing	3	3.8
Unusually fast heartbeat	3	3.8
Diarrhea	3	3.8
Fear	3	3.8
Itchy eyes	3	3.8
Metallic taste in mouth	3	3.8
Tightness in chest	2	2.6
Abdominal cramps/pain	2	2.6
Headache	2	2.6
Passing out	1	1.3
Disoriented	1	1.3
Anxiety	1	1.3
Teeth itching	1	1.3
Out of body experience	1	1.3

*Some respondents had more than one answer

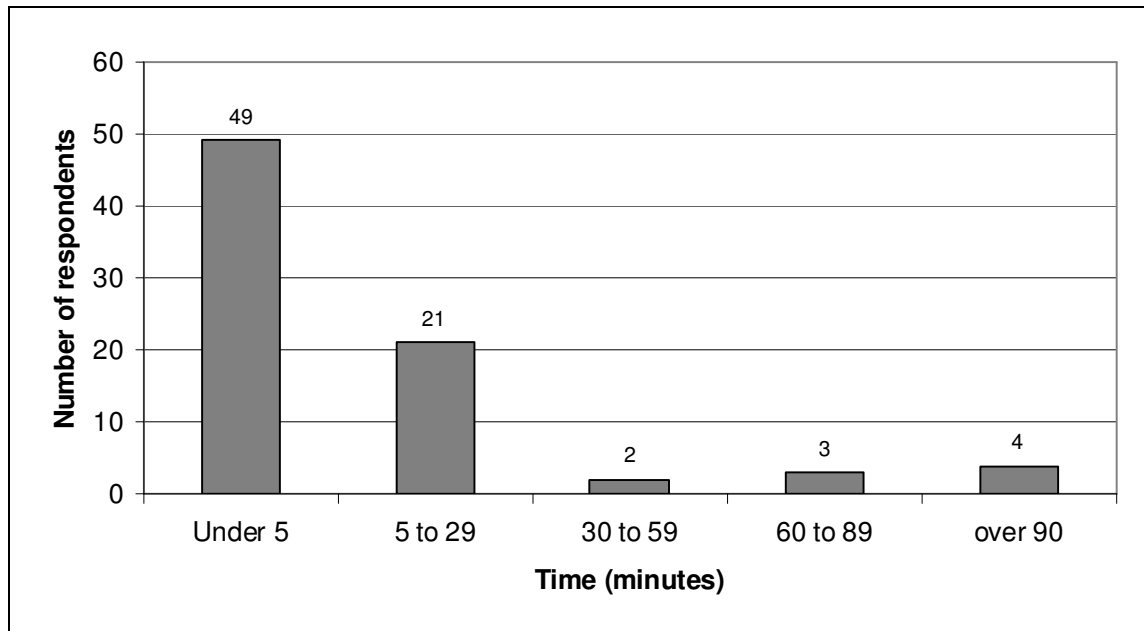


Figure 6: Time (in minutes) at which symptoms begin after eating the suspect food (n = 80)

3.5 Treatment

Eleven respondents have been hospitalized for a food allergy reaction. Two thirds (66%) have been hospitalized three times or less; though one individual has been admitted to the hospital more than ten times. Half (54%) of these occurrences happened when the subject was under the age of 20, and four have had to be intubated during treatment. A larger number (63%) of people were treated in an emergency room (ER), with more than half (53%) only having one visit (Figure 7). The age for ER visits were spread out over the age range and can be found in Figure 8. During the oral interview, subjects were asked to remember the most severe reaction that they could clearly recall. The majority (70%) sought emergency treatment, though 30 percent administered self treatment (Figure 9).

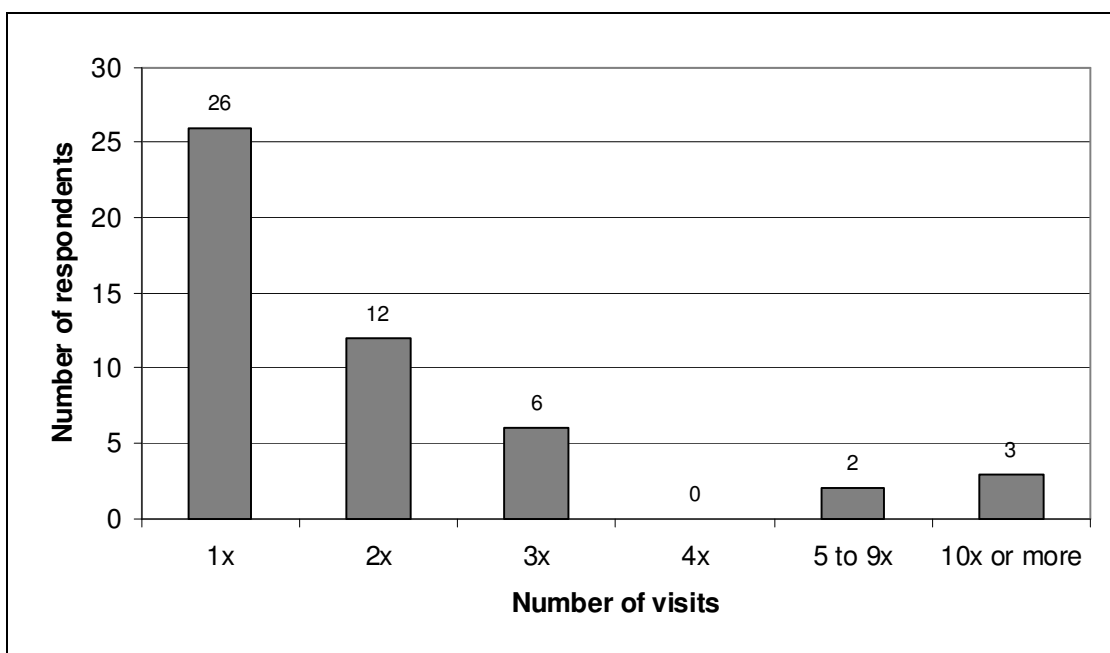


Figure 7: Frequency of emergency room admittance for food allergy reactions (n = 50)

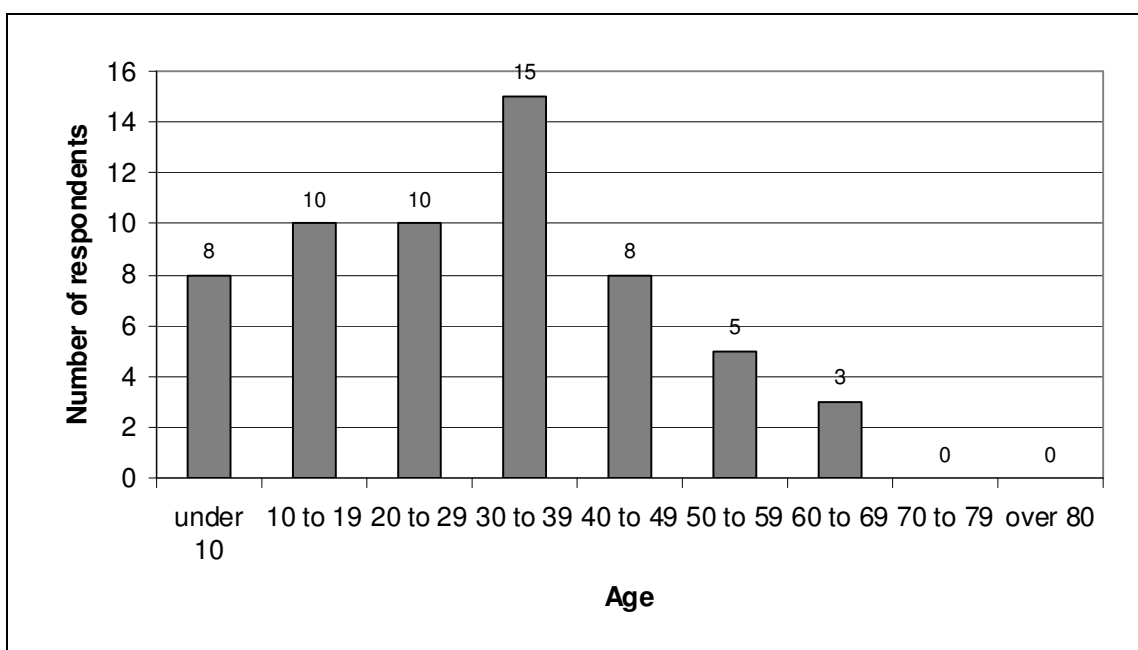


Figure 8: Age at emergency room visit* (n = 50)

*Some participants had multiple responses

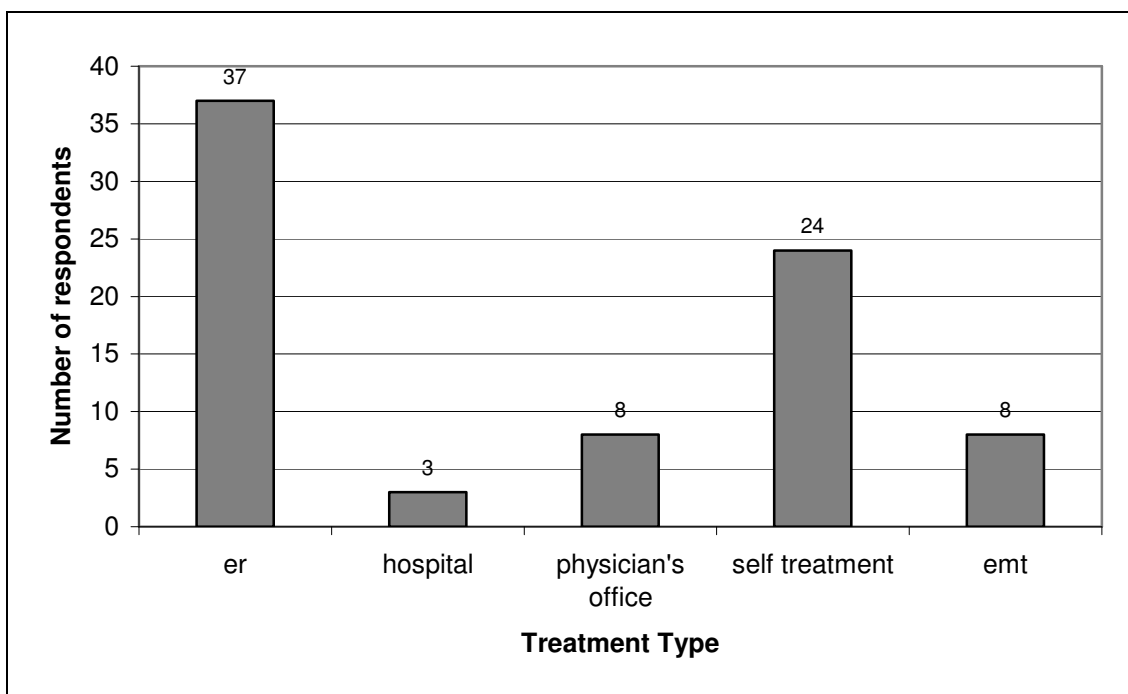


Figure 9: Type of treatment sought at worst reaction remembered (n = 80)

Respondents described their feelings about those allergic reactions as “panicked,” “unsure,” “terrified,” “embarrassed,” and “impending doom.” Subjects also expressed a feeling of not knowing what was going on, which caused some to be fearful and others to be unconcerned because they were unaware of the severity of their symptoms at the time. Additional answers can be found in Table 2. When asked to rate how concerned they felt about their worst reaction remembered, the average for all respondents was quite high, 8.01 on a scale of 10 (from low to high) (Figure 10), with an average severity rating of 7.49 for that reaction (Figure 11).

Table 2: Description of how subject felt during worst reaction that could be clearly remembered and number and percentage with same descriptor*. Elaborations can be found in bulleted lists. (n = 80)

Description	N	Percent
Panicked <ul style="list-style-type: none"> • “Freaking out” • Would do anything to feel better • Because parents did • Because not at home 	23 2 1 1 1	28.8
Unsure/Nervous <ul style="list-style-type: none"> • Didn’t know what was happening • Never felt that way before • Didn’t know how much eaten 	18 9 4 1	22.5
Worried/Concerned <ul style="list-style-type: none"> • Thought if Benadryl was taken, would be fine • Never as severe before • Because could get worse 	13 1 1 1	16.3
Terrified/Fearful	9	11.3
Relatively calm <ul style="list-style-type: none"> • Because was with parents • “Didn’t have a clue” • Distracted • Knew it was an allergic reaction 	9 2 2 1 1	11.3
Felt like I was going to die	3	3.8
Anxious	3	3.8
Impending doom	2	2.5
Confused	2	2.5
Aggravated	1	1.3
Embarrassed	1	1.3
Uncomfortable about appearance	1	1.3

*Some participants had more than one answer

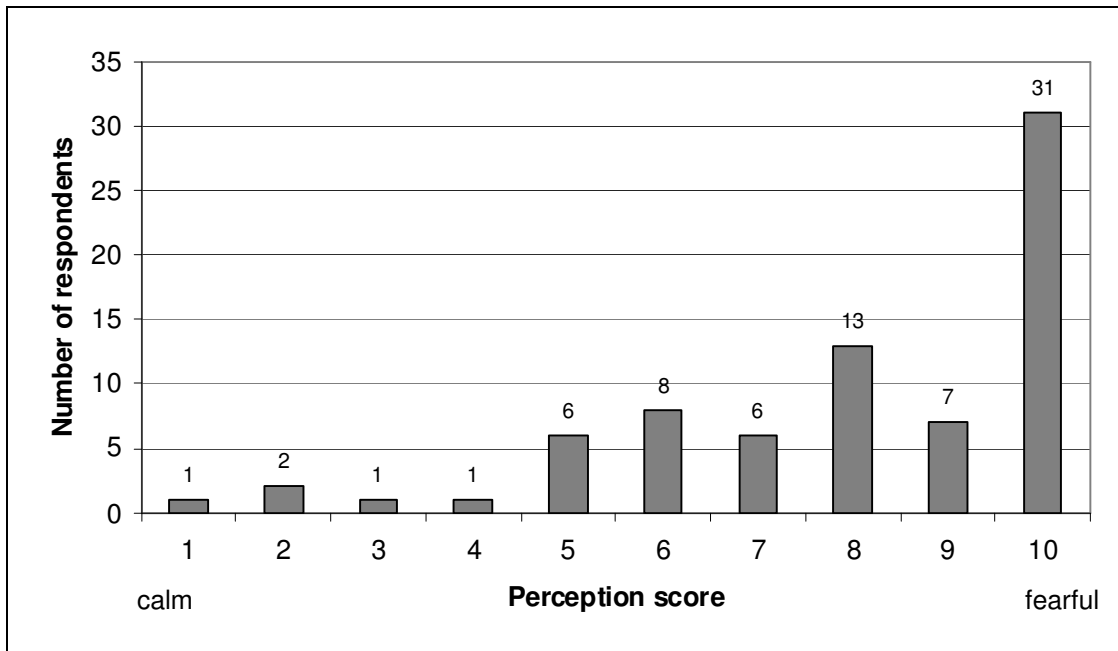


Figure 10: Feeling of fear during worst reaction remembered (n = 80)

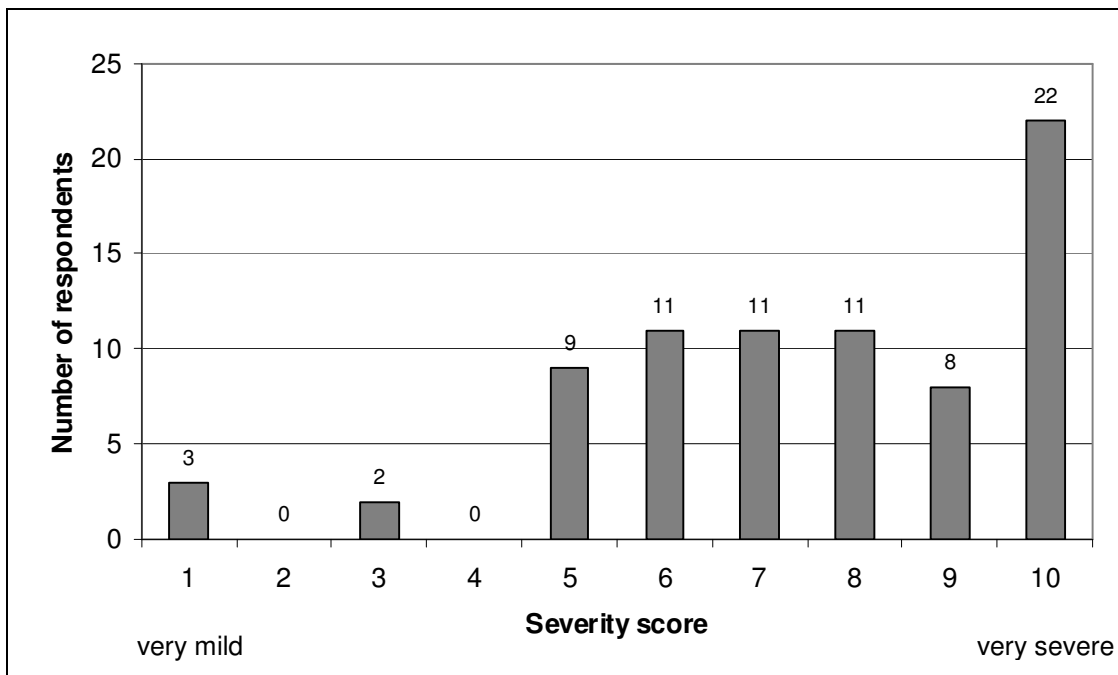


Figure 11: Perceived severity of worst reaction remembered (n = 80)

3.6 Medical Personnel

The majority (91%) of subjects have been told they have a food allergy by a physician with nearly equal numbers being told by a primary care physician (44%) as by an allergist (40%) (Figure 12). In most cases (94%), after initially being diagnosed with a food allergy, all of the participants' primary care doctors were made aware of the participant's allergy, and 95 percent of the subjects' current primary doctors are aware. Most participants (95%) felt very comfortable (a rating of 8 or higher on the comfort scale) discussing food allergy with their physician and bringing up concerns they may have (Figure 13). Having a physician inform them of their allergy made participants more comfortable discussing food allergy ($p = 0.005$). A number of factors including:

- training by medical personnel on, or review of, how to use an auto injector
- being given a plan of action
- receiving information about why the body reacts the way it does
- learning to which foods they were allergic, how to avoid allergenic foods, and how to read labels on food packages
- getting information about allergy symptoms about which to be concerned from a physician
- having consulted an allergist
- being a FAAN member
- gender of the respondent

do not have an effect on participants' comfort level with their doctor. About 22 percent of individuals felt a doctor along the way had downplayed their food allergy. In these instances, respondents explained that the doctor had compared the food allergy to a seasonal allergy or had told the patient that they did not believe it to be a true food allergy (Table 3).

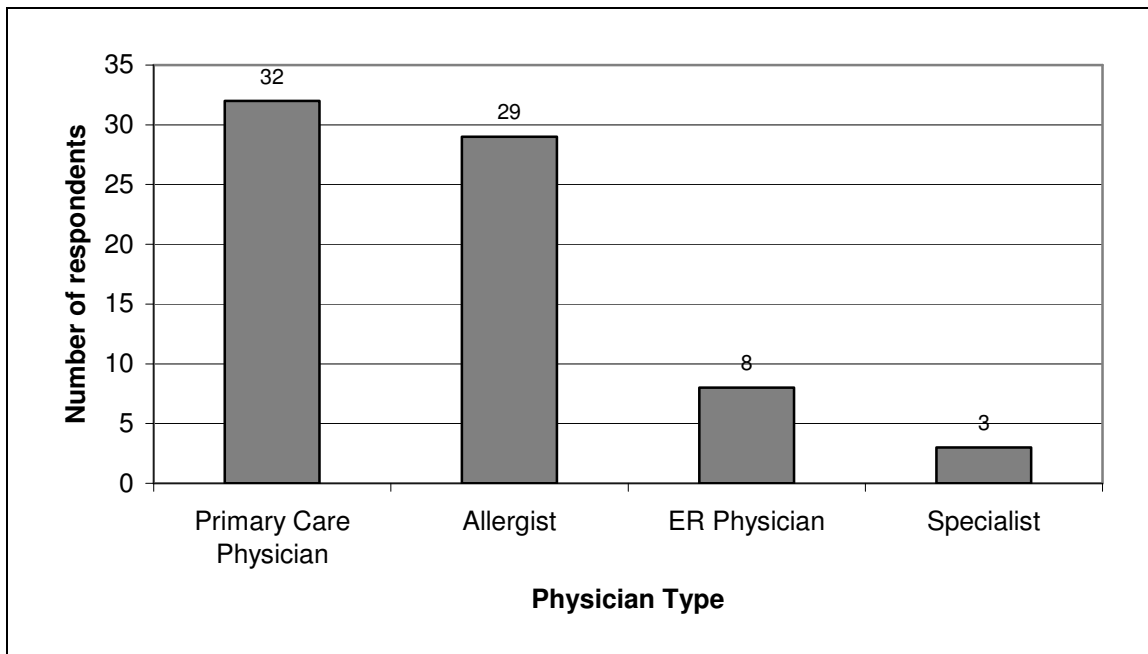


Figure 12: Type of physician who first told subjects they had a food allergy (n = 72)

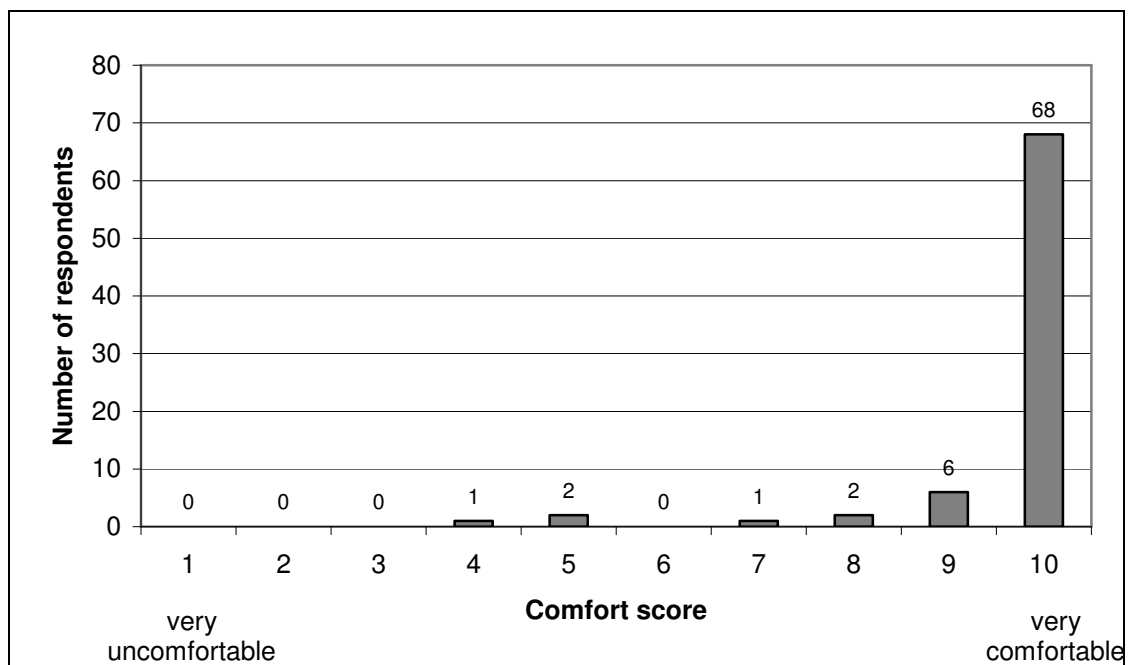


Figure 13: Comfort level discussing food allergy with physician and bringing up concerns (n = 80)

Table 3: Detailed reasons why participants felt that a physician had downplayed their food allergy (n = 12)

Expanded reasons for feeling that food allergy was downplayed by a physician
<ul style="list-style-type: none"> • Told “don’t have a ‘real’ allergy” by specialists • Didn’t think it was a food allergy • Didn’t require an epinephrine prescription • Unsupportive, non-specific advice, unrealistic plan of action • Told “who knows?” in regards to why allergy developed • Unwilling to be decisive • Told was just upset, only to have reaction shortly after • Told true food allergies are rare, so probably didn’t have one • Compared to seasonal allergies • Asked “how allergic do you think you are?” in regard to egg allergy and vaccines • Told “allergies are hard to treat” when asked what to do • Didn’t feel it was relevant to general health

When asked to recall an interaction with medical personnel that occurred during a reaction requiring emergency care, only 42 percent were informed at that time by medical personnel that what they experienced was a life-threatening allergic reaction. Of the ten participants informed more specifically about the severity of their reaction by medical personnel, most ranked the severity at the upper end of the scale (avg 8.3) (Figure 14). At this occurrence, 65 percent of subjects were encouraged to make a follow up appointment with a physician to discuss the reaction and a future course of action. Most participants (89%) had a follow up appointment with either a primary care physician or allergist where all of them discussed their specific food allergy. Of the respondents who were treated at the ER and not encouraged to make a follow up appointment, or who were encouraged, but did not immediately set up an appointment, 82 percent did eventually inform their doctor that they had a severe food allergy.

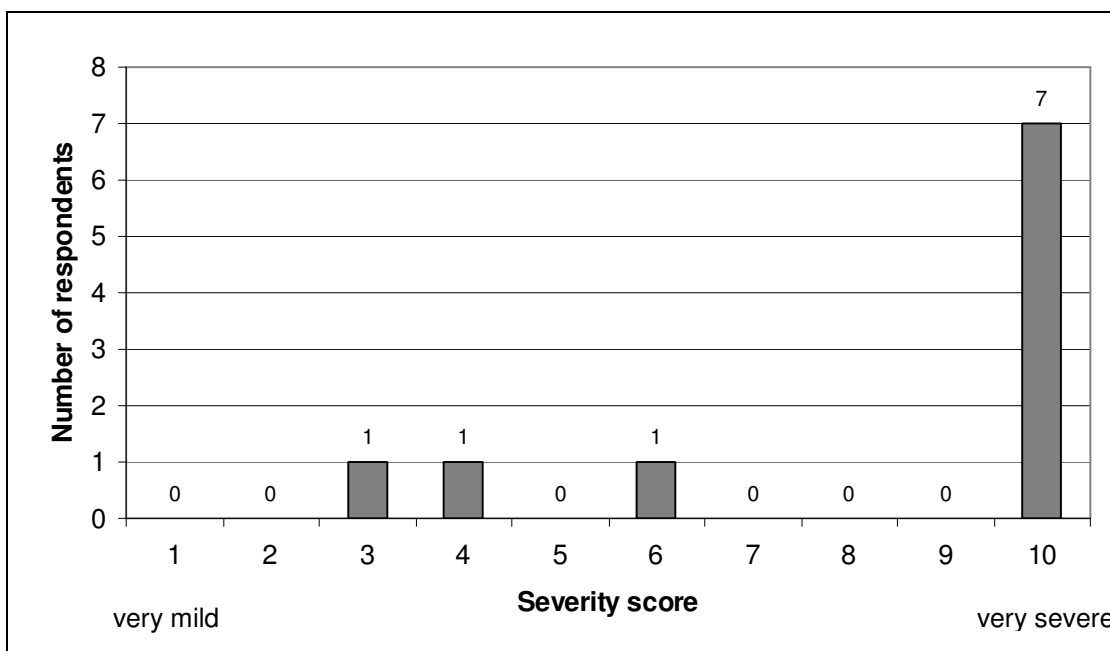


Figure 14: Severity of reaction as determined by doctor or nurse at an emergency visit (n = 10)

Of participants who carry an epinephrine auto injector, 89 percent reported that their current doctor was aware that they have a severe food allergy that requires the use of epinephrine. Approximately half (49%) of subject's physicians discussed the need to renew the epinephrine auto-injector prescription every year. Only 33 percent of the respondents said that their physician reviewed how to use an auto-injector to make the patient feel confident and comfortable using it in an emergency situation

3.7 Information Received

Slightly more than half of the subjects (54%) were told about or given any information by medical personnel about allergy symptoms with which they should be concerned. Allergists supplied this information to 66 percent of respondents. All were supplied with a verbal explanation of symptoms, which was accompanied by written instructions 25 percent of the time. The majority of participants (89%) were told a

medical term used to describe a severe allergic reaction, such as anaphylaxis. When asked to consider their confidence in the information supplied by medical personnel about allergy symptoms with which to be concerned, subjects spanned the response scale with the majority answering on the higher end of the confidence scale (avg 8.37) (Figure 15). Having a physician inform participants of their food allergy, consulting an allergist and gender of respondent did not affect confidence scores.

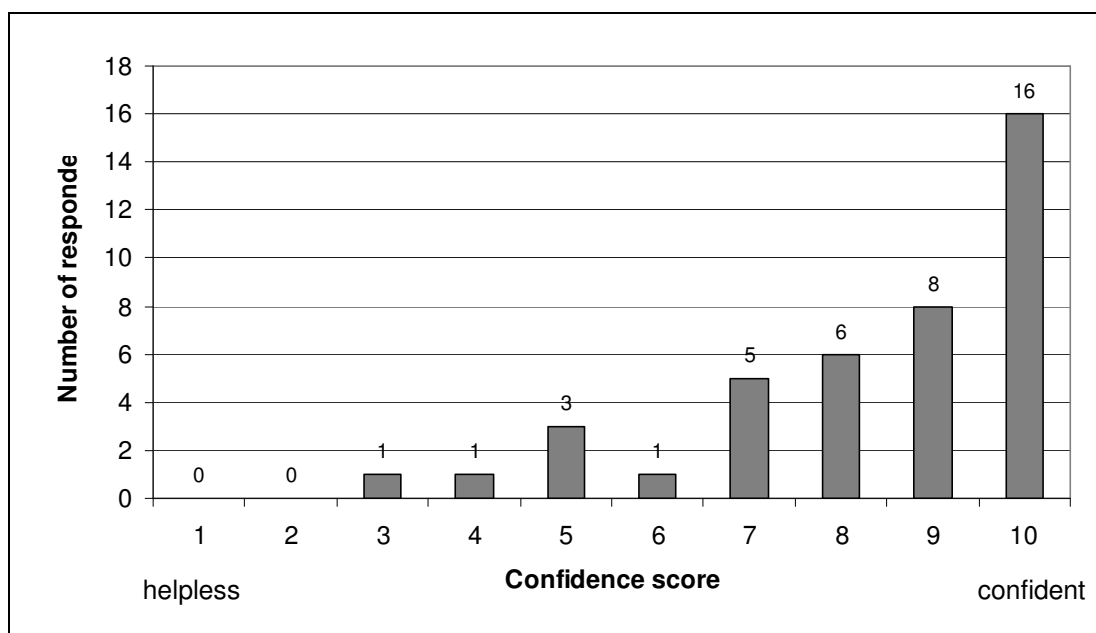


Figure 15: Confidence regarding information given by medical personnel about allergy symptoms with which to be concerned (n = 41)

Subjects were asked for suggestions that could improve how they were informed or taught to take care of a severe reaction from medical personnel. The most common responses were for additional information and educational materials regarding symptoms and treatment, more detailed plans of action, and more training with self-injectable epinephrine (adrenaline). Recommendations were made for a combination of written and verbal information, as well as video demonstrations of what to do if a reaction occurred (Table 4).

Medical personnel gave less than half (44%) of the subjects information to help them understand the mechanics of food allergy and how and why the body reacts. An allergist was the most common (91%) source of this information, which was supplied through a verbal explanation (89%) and/or written instructions (46%). Fewer individuals (29%) were given information about sources where they could find out more information about food allergy on their own, and most (91%) were referred to websites. Three quarters (75%) of subjects have looked up information on their own to help understand food allergy and how and why the body reacts, with websites being the most common (93%) source, with additional information provided by books and support groups. Participants' confidence in the information they had obtained was on the high end of the confidence scale with an average of 7.56 (Figure 16). Participants' confidence in food allergy education information is not affected by:

- being a FAAN member
- being hospitalized or admitted to the ER
- being informed by medical personnel of a food allergy
- consulting an allergist
- gender of the respondent
- being told the information by medical personnel
- or looking up information on their own.

Conversely, their comfort in receiving the information about their allergy (avg 3.27) and how knowledgeable they feel about understanding why their body reacts to certain foods (avg 5.61) ranged across the respective scales (Figures 17 and 18). Female respondents were significantly less calm receiving information about their allergy ($P = 0.019$), though consulting an allergist did not effect calmness.

Table 4: Participants suggestions for improving how they were informed or taught to take care of a severe reaction from medical personnel (n = 55, 25 NR)

Suggestion	N	Percent
More information/education	24	43.6
<ul style="list-style-type: none"> • Severity of reaction • Symptoms to watch for • Available medications to use • Precautions to take • Video instructions • Cross contamination 	6 4 2 2 1 1	
Plan of action	20	36.4
<ul style="list-style-type: none"> • When to use and how much of which medications • Logical course of action • When to go to emergency room 	9 4 3	
Written instructions	16	29.1
<ul style="list-style-type: none"> • Pamphlet with timeline of what is happening to the body and timeline of how medication affects the body • List of possible/common symptoms • Tips on how to live with a severe food allergy • List of additional resources • Guidelines on what to do when reaction occurs 	3 3 2 1 1	
Training	12	21.8
<ul style="list-style-type: none"> • How to use EpiPen® • Use of EpiPen® trainer • Told to go to emergency room if EpiPen® is used • Walk through possible scenarios 	4 1 1 1	
Verbal instructions	12	21.8
Training for medical personnel	10	18.2
<ul style="list-style-type: none"> • Review allergy with patient periodically • Discuss whether current plan is correct for specific allergy • Go over current treatment/management with patient • General practitioners should be more familiar with food allergies 	5 3 2 2	

*Some subjects had more than one answer

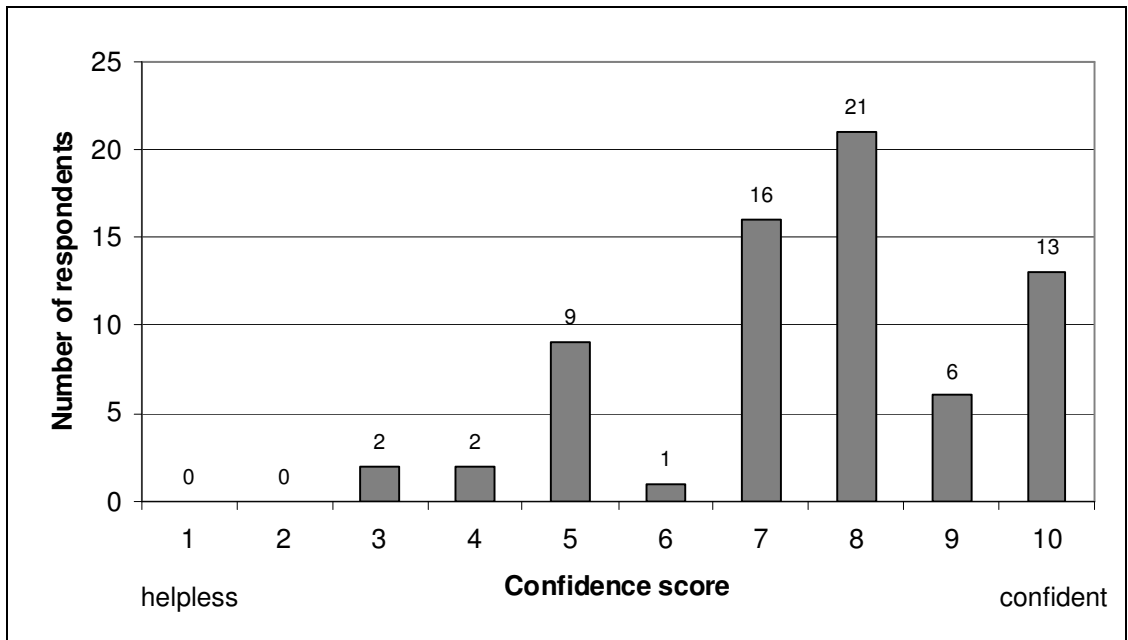


Figure 16: Confidence in information about food allergies received from medical personnel and/or obtained from independent research (n = 70)

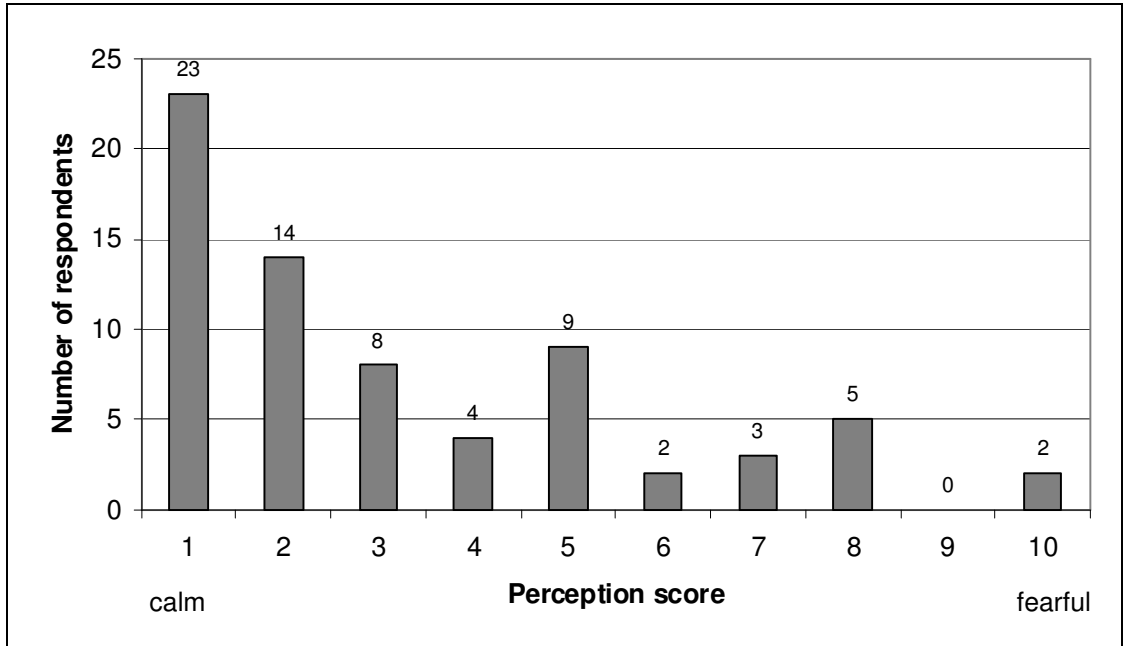


Figure 17: Calmness receiving information about food allergy mechanics and how and why the body reacts (n = 70)

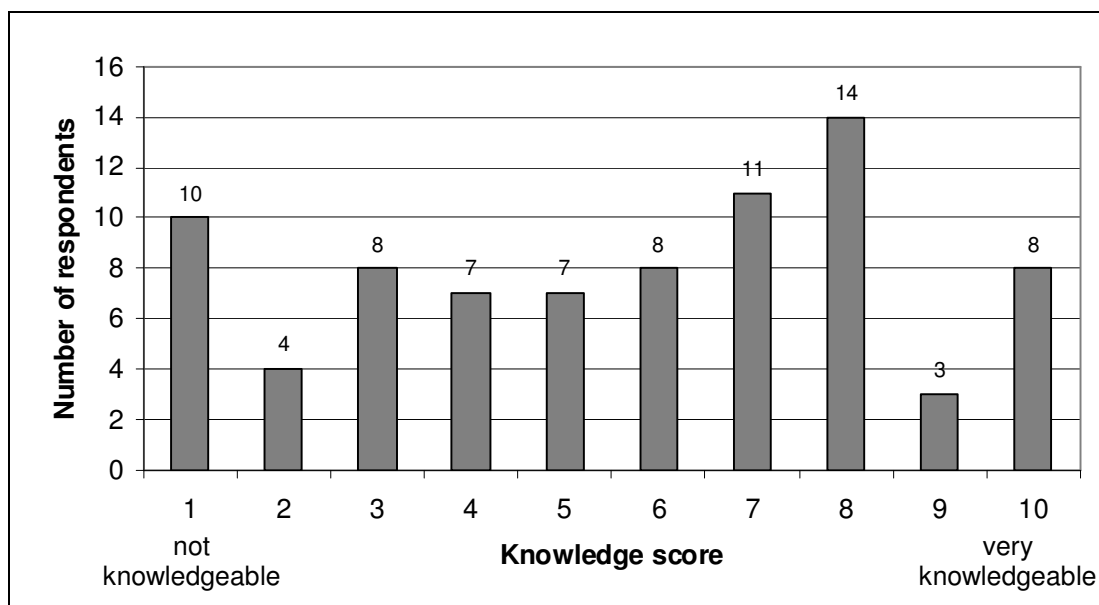


Figure 18: Knowledge about understanding why the body reacts to certain foods (n = 80)

Participants' knowledge scores were not affected by:

- FAAN membership
- being given information about food allergies
- being hospitalized or admitted to the ER
- being informed of their food allergy by a physician
- consulting an allergist
- or gender of the respondent.

Looking up information on their own did significantly increase participants' knowledge scores. The majority of subjects (86%) felt the information they received from medical personnel and their own research was helpful in motivating them to understand why it is important to avoid foods and have a plan of action to follow in case a severe reaction occurs. About 90 percent of the respondents felt they used this information in their daily life. The most common response to what participants thought was the most helpful information they have ever received was being told to

avoid the foods to which they were allergic. Additional responses are found in Table 5.

Almost all respondents (95%) were told to avoid foods to which they were allergic, though only 36 percent were taught how to avoid those foods and only 30 percent were taught how to read labels on food packages. Approximately one quarter (24%) of the participants were shown a list specific to their allergen that showed foods that might contain or have come in contact with that allergen. The majority of participants (94%) have heard about the problem of cross contamination, and 62 percent have had a reaction due to it. While only two subjects do not go out to eat in restaurants, 80 percent of participants have had a reaction in a restaurant. Three quarters of respondents (79%) have heard ways to avoid allergenic foods in restaurants, though 83 percent said they are self-educated. Participants who were educated on how to avoid foods, and situations where foods could cause a reaction, were moderately confident (avg 7.30) with the information provided and felt knowledgeable (8.30) about being able to avoid the offending food(s) (Figures 19 and 20).

Confidence in education on avoiding foods is significantly increased if the participant has heard about cross contamination ($p = 0.017$). A number of factors including:

- hearing about how to avoid allergenic foods in restaurants
- being a FAAN member
- being hospitalized or admitted to the ER for an allergic reaction
- gender of the respondent
- being shown a list of food ingredients derived from the participants' allergen
- being taught to avoid, and how to avoid, the foods they are allergic to
- being taught to read food labels by medical personnel

Table 5: The most helpful information participants received about their food allergy (n = 74, 6 NR)

Advice	N	Percent
Don't eat suspect food	14	18.9
Severity of food allergy	8	10.8
• Small amount can kill you	2	
• Doctor used a scare tactic	1	
Being told what allergic to	7	9.5
• Skin/blood tests	3	
Told how to read food package labels	7	9.5
• How food is processed	1	
• FALCPA information	1	
• Know that food ingredients can change	1	
How a reaction happens, what happens in your body	5	6.8
• Histamine reacts with a protein	1	
Receiving/carrying an EpiPen®	5	6.8
How to use EpiPen®	4	5.4
Plan of action from a physician	3	4.1
Newsletter with tips (e.g. FAAN)	3	4.1
Reaction can be caused by other pathways than ingesting the allergen	2	2.7
Inform food service personnel of allergy/question preparation	2	2.7
Told allergies can be linked by the plant family to which it belongs	2	2.7
Get to a doctor as soon as possible if having a severe reaction	2	2.7
More severe reactions can be caused by interaction of foods/situation	1	1.4
Told what cross contamination is	1	1.4
Told what symptoms to watch for	1	1.4
Cooking replacements for allergen	1	1.4
Trial and error can work in determining what foods can be eaten	1	1.4
Don't use EpiPen® unless necessary	1	1.4
Timeline of how long reaction should be observed	1	1.4
Told to read <i>The Impossible Child in School – At Home: A Guide for Caring Teachers and Parents</i> by Doris Rapp	1	1.4
Being told that antihistamines may be effective before use of EpiPen®	1	1.4

*Some subjects had more than one answer

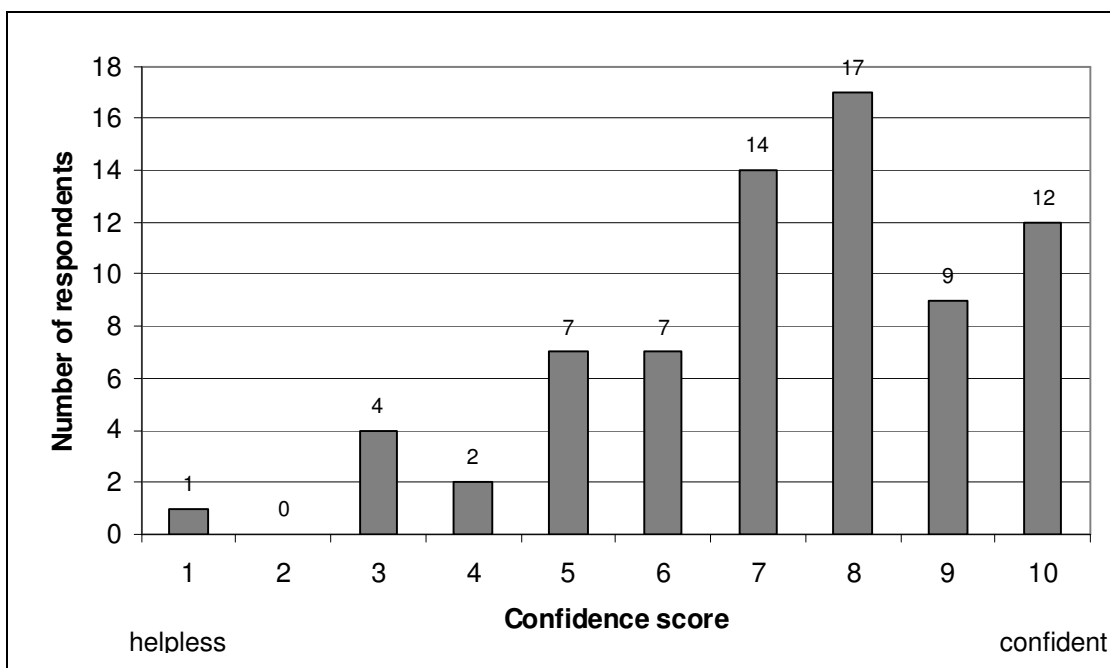


Figure 19: Confidence following education: ability to avoid foods and situations where foods could cause a reaction (n = 73)

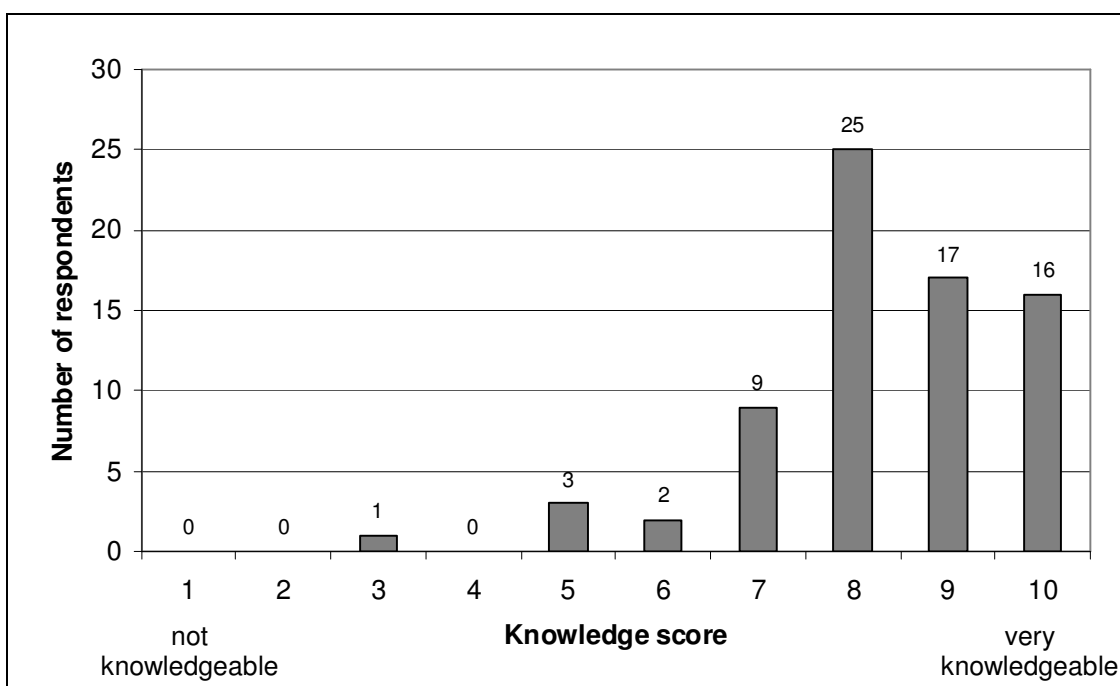


Figure 20: Knowledge level of being able to avoid foods if education was received (n = 73)

- being informed of an allergy by a physician
- or consulting an allergist

do not affect participants' confidence in education about being able to avoid foods.

Being taught to read labels on food packages by medical personnel is the only factor from the above list that increases participants' knowledge score on being able to avoid foods.

Comfort discussing food allergy needs with waiters and other food service workers in a restaurant spans the comfort scale, with the average being 7.39 (Figure 21). Having a reaction in a restaurant, hearing about how to avoid allergenic foods in restaurants, discussing food allergy with an allergist and gender do not affect participants' comfort level discussing food allergy needs with food service personnel.

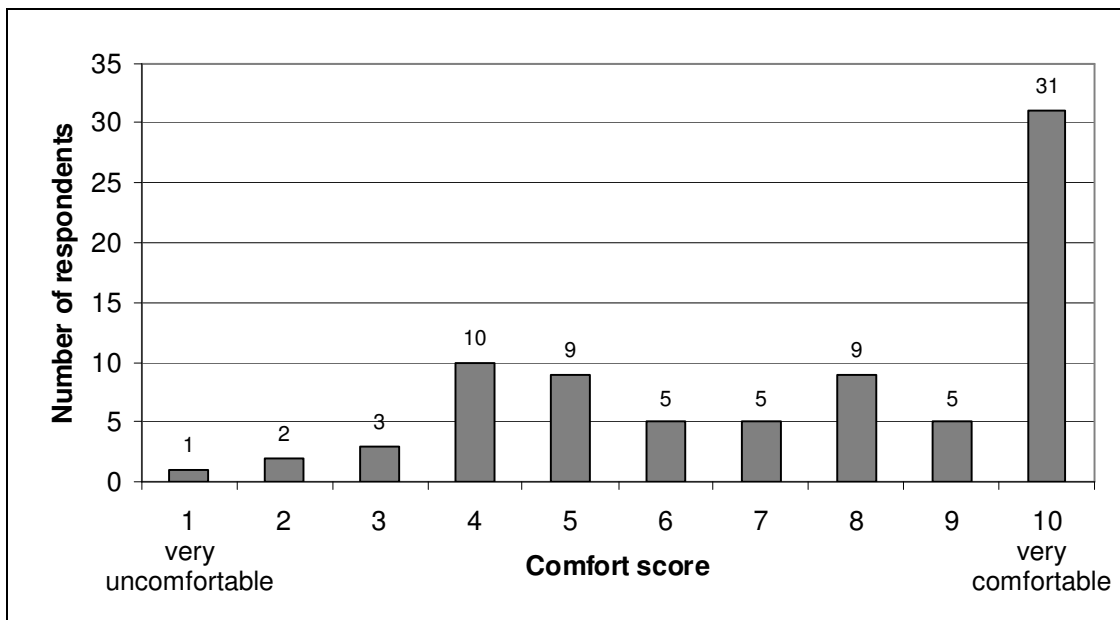


Figure 21: Comfort discussing food allergy needs with waiters and other food service workers in a restaurant (n = 80)

Participants were very confident (9.13) about being able to avoid having a severe reaction by carefully avoiding foods at home, though their confidence

on being able to avoid having a severe reaction by carefully avoiding foods away from home was significantly lower, averaging 6.58 ($p = 0.000$) (Figures 22 and 23).

Being a FAAN member ($p = 0.014$), having a physician inform them of their food allergy ($p = 0.001$), and hearing about the problem of cross contamination ($p = 0.000$) significantly increase participants' confidence in avoiding a severe reaction at home. Hearing of cross contamination ($p = 0.013$), being taught to read labels on food packages by medical personnel ($p = 0.046$) and being male ($p = 0.002$) significantly increase participants' confidence in avoiding severe reactions away from home.

Factors that do not affect participants' confidence scores include:

- being told to avoid the foods they are allergic to by medical personnel
- being taught to avoid those foods by medical personnel
- being shown a list of food ingredients derived from or containing their food allergen from medical personnel
- being hospitalized or admitted to the ER
- consulting an allergist.

In an open-ended interview question, study participants suggested ideas that they thought could improve how food avoidance is being taught or explained. Most focused their suggestions on improving avoidance in restaurants, grocery stores and schools. Improvements included ideas such as: menus should be better labeled, severity of food allergy should be taught in educational programs in schools and restaurants, and cross-contact should be demonstrated to people who work directly with foods (Table 6).

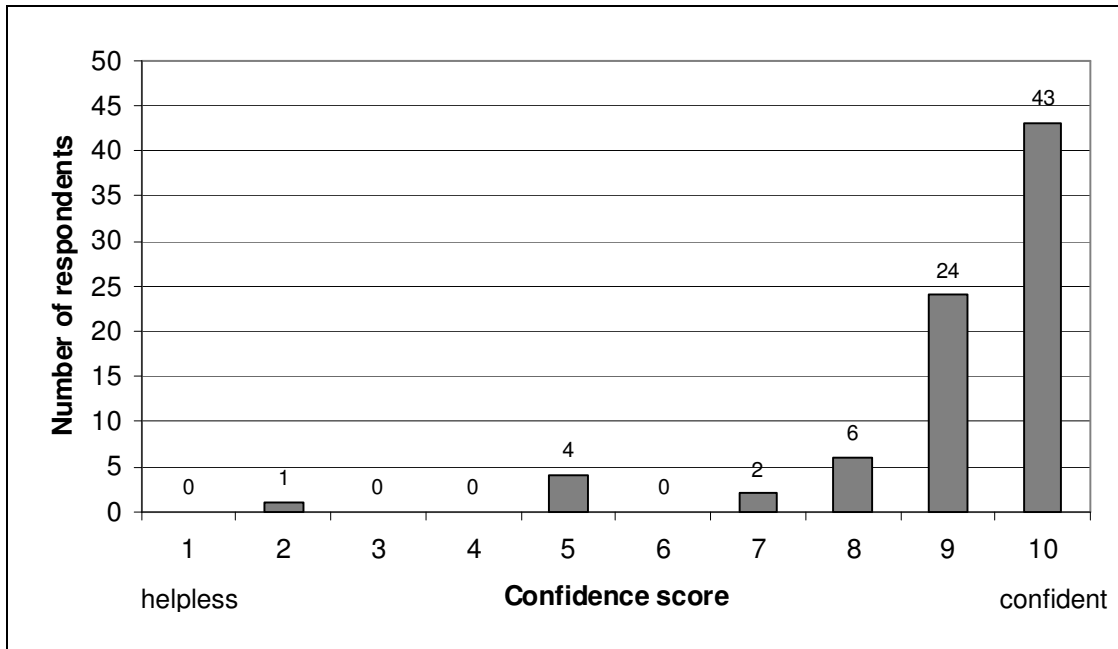


Figure 22: Confidence in ability to avoid having a severe reaction by carefully avoiding foods at home (n = 80)

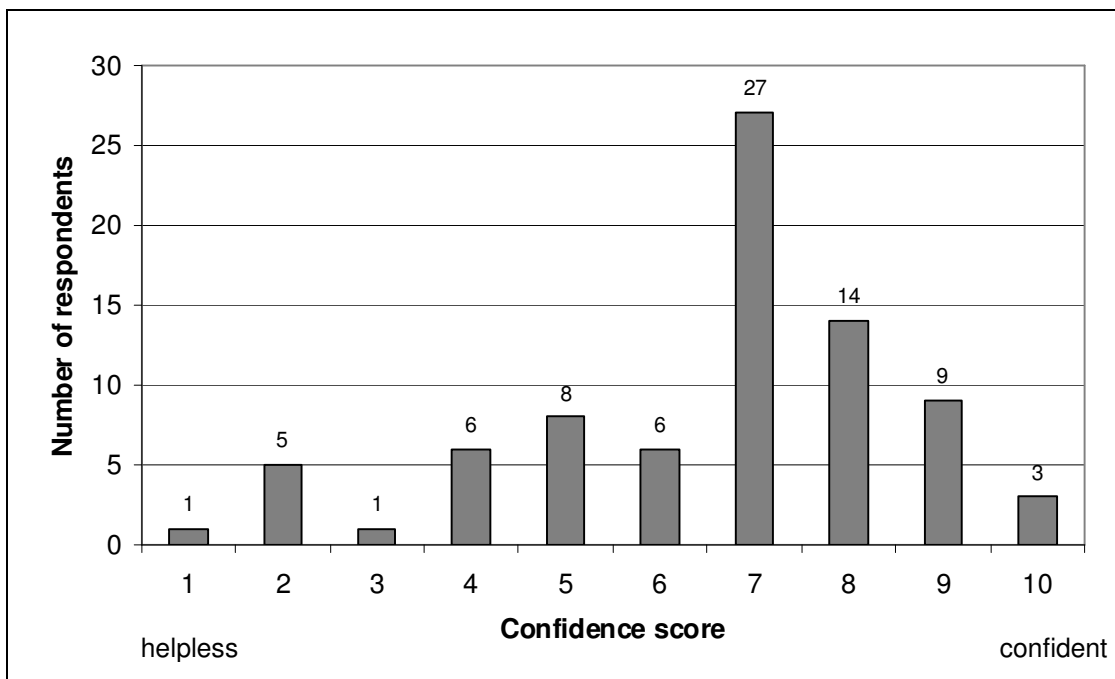


Figure 23: Confidence in ability to avoid having a severe reaction by carefully avoiding foods away from home (n = 80)

Table 6: Suggestions for improvement of how food avoidance is being taught or explained* (n = 65, 15 NR)

Improvement	N	Percent
More written information <ul style="list-style-type: none"> • Foods/cuisines to avoid • How food is processed • How to talk to restaurant personnel • Non-food items that might contain allergens 	19 6 3 2 2	29.2
Increased information in food establishments <ul style="list-style-type: none"> • Food service personnel training • Menu labeling • Grocery store displays • Incorporation of food allergy/cross contamination into health inspection 	17 7 3 1 1	26.2
Training on reading food labels <ul style="list-style-type: none"> • List of ingredients that might be derived from allergen (e.g. FAAN list shown in interview) 	11 9	16.9
More information provided by physicians <ul style="list-style-type: none"> • In lay terms 	8 1	12.3
Educational programs in schools	7	10.8
Cross contamination explained	6	9.2
Informing the general public <ul style="list-style-type: none"> • Public service announcements 	3 1	4.6

*Some participants had more than one answer

3.8 Plan of Action

An emergency plan of action, a set of instructions that informs patients about what to do and which medications to take if a reaction occurs, was only given by medical personnel to one third (34%) of participants. Most of these plans (71%) were provided to respondents by an allergist. Subjects were asked to describe their prescribed or self-developed plan of action and almost all respondents (99%) mentioned calling 911 or going to the ER, while 68 percent included the use of self-injectable epinephrine in their plan and 68 percent would use an antihistamine. Most

were confident in using their plan of action (avg 8.03), though some answered in the mid-range of the scale (Figure 24).

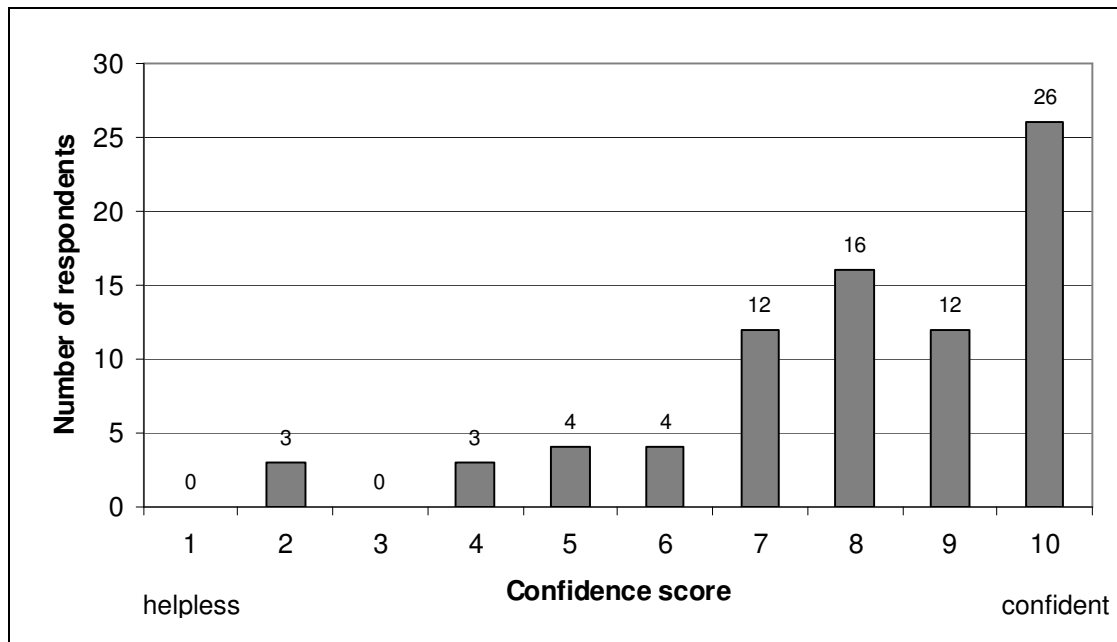


Figure 24: Confidence in using prescribed or self-developed plan of action (n = 80)

Not having a physician inform them of their food allergy ($p = 0.048$), consulting an allergist ($p = 0.023$), being hospitalized ($p = 0.030$) or being admitted to the ER ($p = 0.012$) significantly increased participants' confidence in using their plan of action. Being given a plan of action from medical personnel did not have an effect on participants' confidence score. Of those that were given a plan of action from medical personnel most were calm when receiving the information (avg 3.73) (Figure 25), though seven were given conflicting plans by different physicians or other medical personnel.

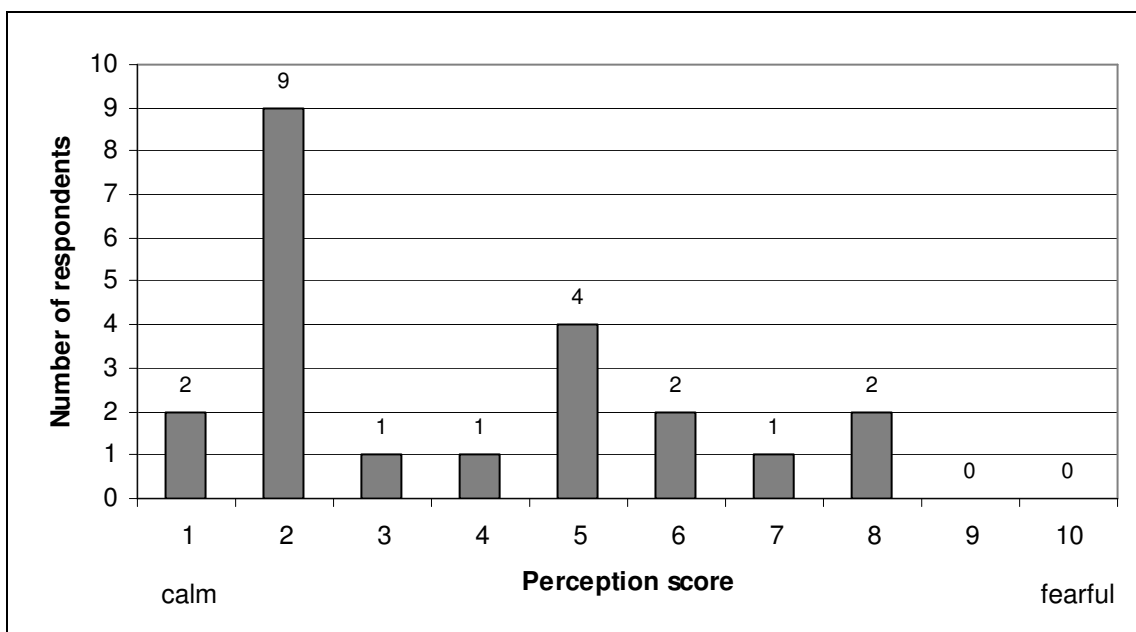


Figure 25: Comfort receiving plan of action information from medical personnel (n = 22)

All of the participants reported that the discrepancy in advice revolved around when epinephrine was to be used. When having a severe reaction, 66 percent used their prescribed plan of action. Respondents believed that having a plan of action (9.66) and having an emergency medication available in case of a severe reaction (9.85) were extremely important (Figures 26 and 27). The following factors:

- being hospitalized or admitted to the ER
- being told of their food allergy by a physician
- consulting an allergist
- or gender of the respondent

did not have a significant impact on participants' importance rating of having a plan of action or emergency medication available.

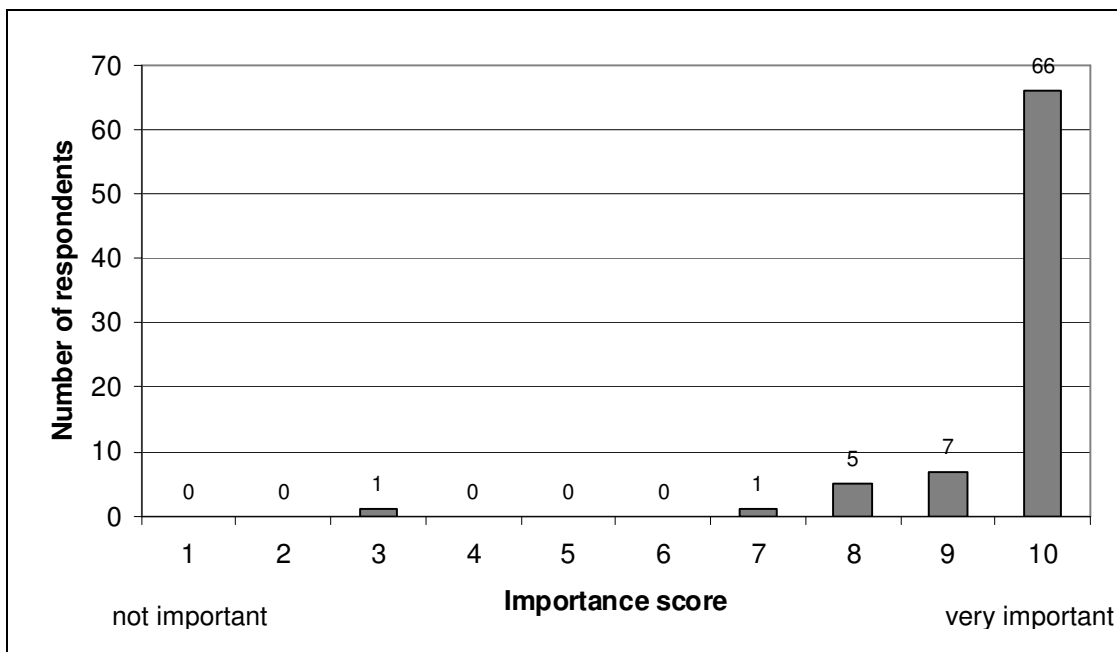


Figure 26: Importance of having a plan of action (n = 80)

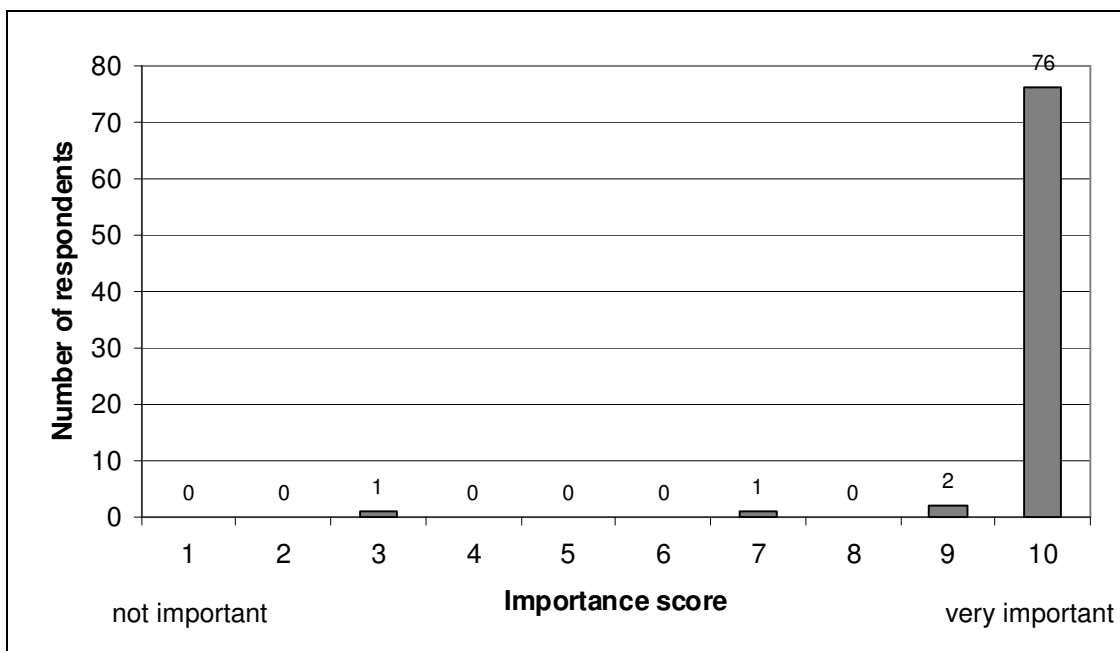


Figure 27: Importance of having an emergency medication available in case of a severe reaction (n = 80)

3.9 Epinephrine and other medications

At emergency room visits, 31 percent of subjects received a self-injectable epinephrine prescription from medical personnel, and 94 percent had that prescription filled. Of those not given a prescription, 32 percent were encouraged to request an epinephrine prescription at a follow up visit with their primary physician or allergist. Most subjects (79%) who had a follow-up visit with a physician, received a prescription from them, and only one person did not have that prescription filled. Of those not prescribed epinephrine, approximately half (43%) have requested a prescription from their physician. The breakdown of how participants obtained their prescription can be found in Figure 28.

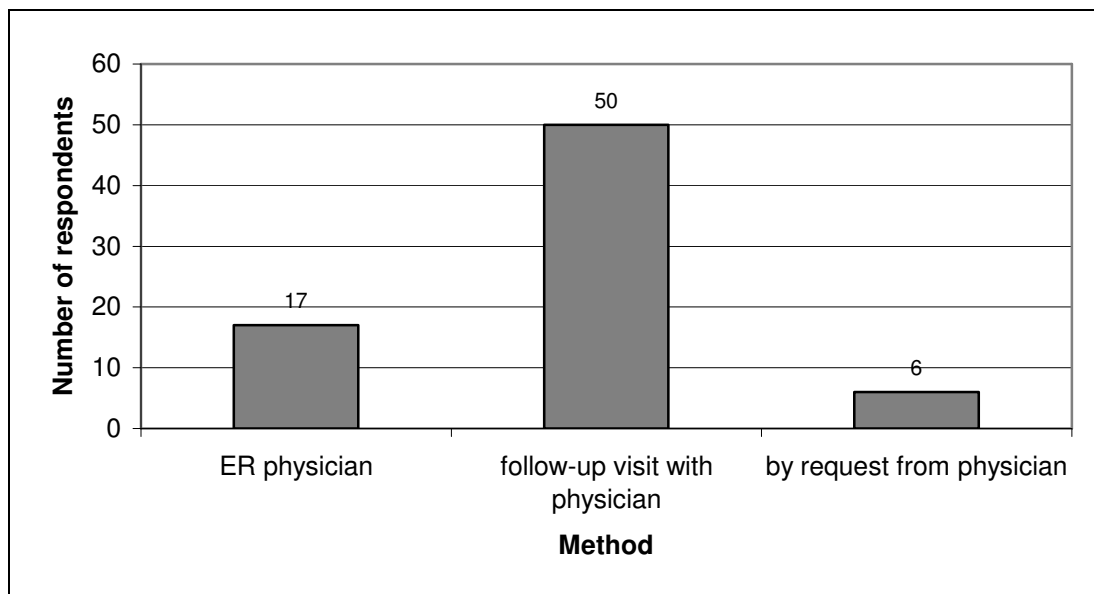


Figure 28: Method of obtaining an epinephrine auto injector prescription (n = 72)

The majority of subjects (83%) were prescribed either one or two epinephrine auto-injectors, though some were prescribed as many as six at a time (Figure 29). Almost three quarters of participants (74%) have their prescriptions refilled every year.

Though 21 percent of people have heard that there is a medical website service that sends a reminder when it is necessary to renew epinephrine prescriptions, only one person uses that service.

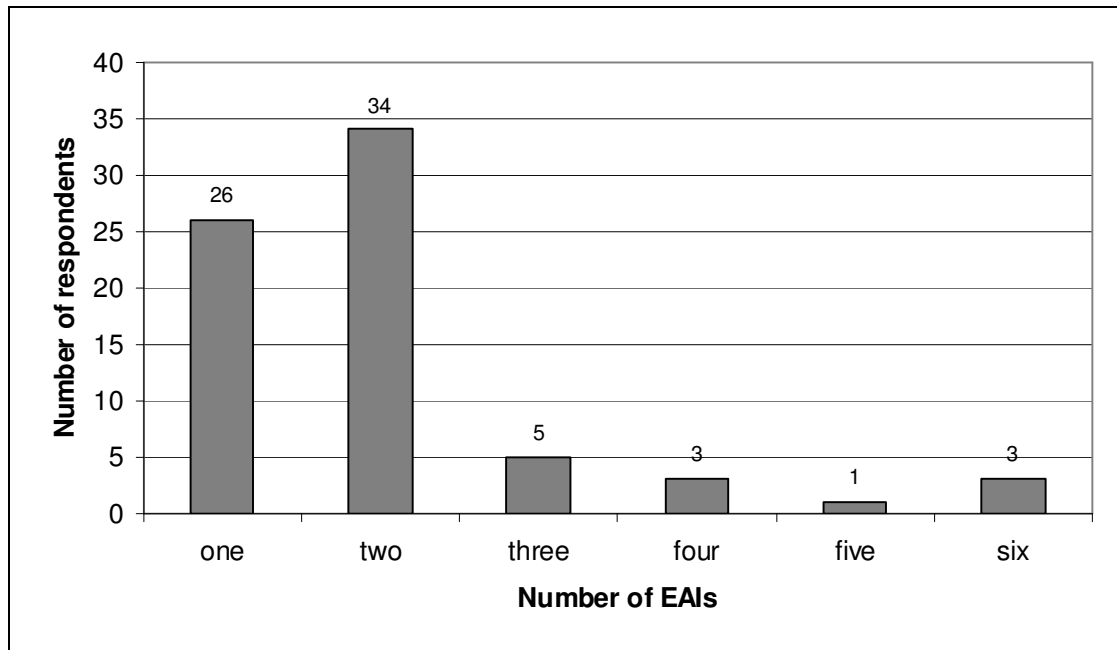


Figure 29: Number of epinephrine auto injectors prescribed at a time to subjects (n = 72)

Approximately half of subjects (51%) prescribed epinephrine carry an auto injector with them at all times, 25 percent carry it with them sometimes, 16 percent carry it only at certain times, and nine percent never carry it (Figure 30). Being a member of FAAN significantly affected how often an auto injector was carried ($p = 0.003$), though being informed by a physician of their allergy, consulting an allergist, being hospitalized or admitted to an ER did not. For those who did not always carry epinephrine with them, the most common reasons were: they are careful about what and where they eat, they forget about it, or they don't have anywhere to put it (Table 7). Only 13 percent of subjects have used an epinephrine auto-injector during a

reaction, and in all cases it has only been used one or two times (Figure 31). More than two thirds of participants (69%) were carrying their auto-injector at the time of the interview.

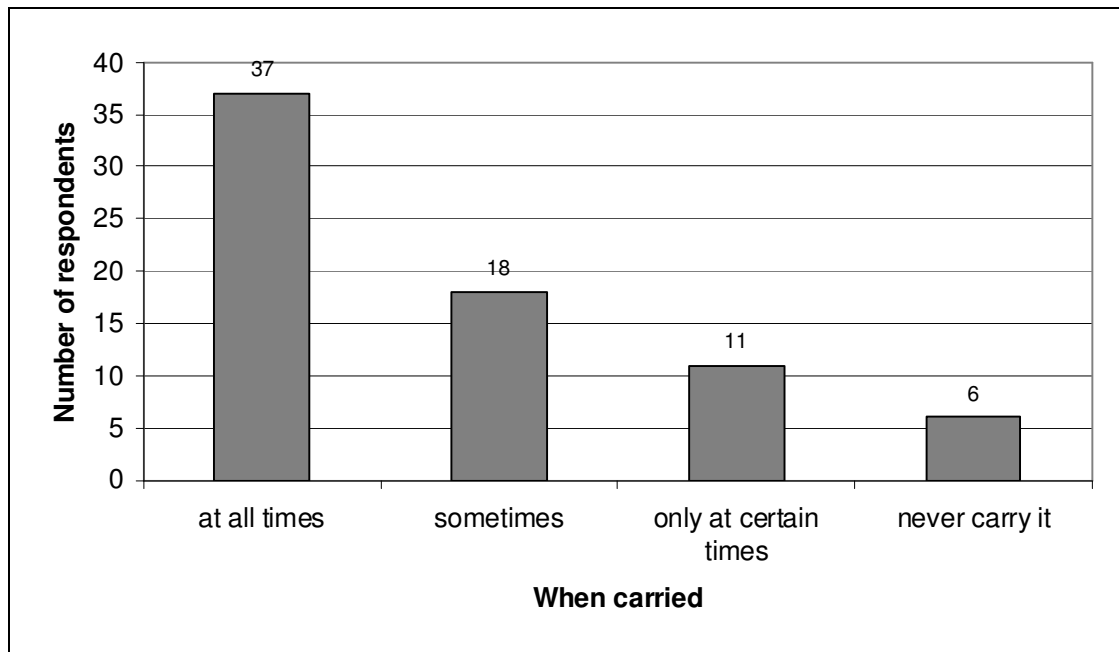


Figure 30: How often participants carried their epinephrine auto injector with them (n = 72)

Three quarters (75%) of the subjects knew why they did not receive an epinephrine prescription from a physician. For 17 percent of participants, epinephrine was discussed, but another medication was given. The responses given for not carrying epinephrine were: the physician felt the allergy was not severe enough (3), patients felt they could manage without carrying epinephrine (2), or they haven't had the opportunity to talk to a physician since a more recent severe reaction (1). In all subjects that did not receive a prescription, their physician was aware of the severe food allergy that they possessed.

Table 7: Participant explanation for not carrying epinephrine with them at all times, if it had been prescribed* (n = 39)

Reason for not carrying	N	Percent
Careful about what/where to eat <ul style="list-style-type: none"> Familiar with eating locations Don't frequently encounter allergen Rely on verbal communication at restaurants 	16 3 2 2	41
Forget about it <ul style="list-style-type: none"> Leave it in a previously carried bag In a rush 	7 1 1	17.9
Don't have anywhere to carry it <ul style="list-style-type: none"> Purse too small 	6 2	15.4
Only carry it when traveling	4	10.3
Have never had to use one	3	7.7
Didn't want to carry one when had a small child	1	2.6
Subconsciously don't want the allergy to exist	1	2.6
Expired and didn't renew it	1	2.6
Don't think it's necessary anymore	1	2.6
Haven't had a reaction in a long time	1	2.6
Never far from a pharmacy	1	2.6
Irresponsible	1	2.6
No reason	1	2.6

*Some subjects had more than one answer

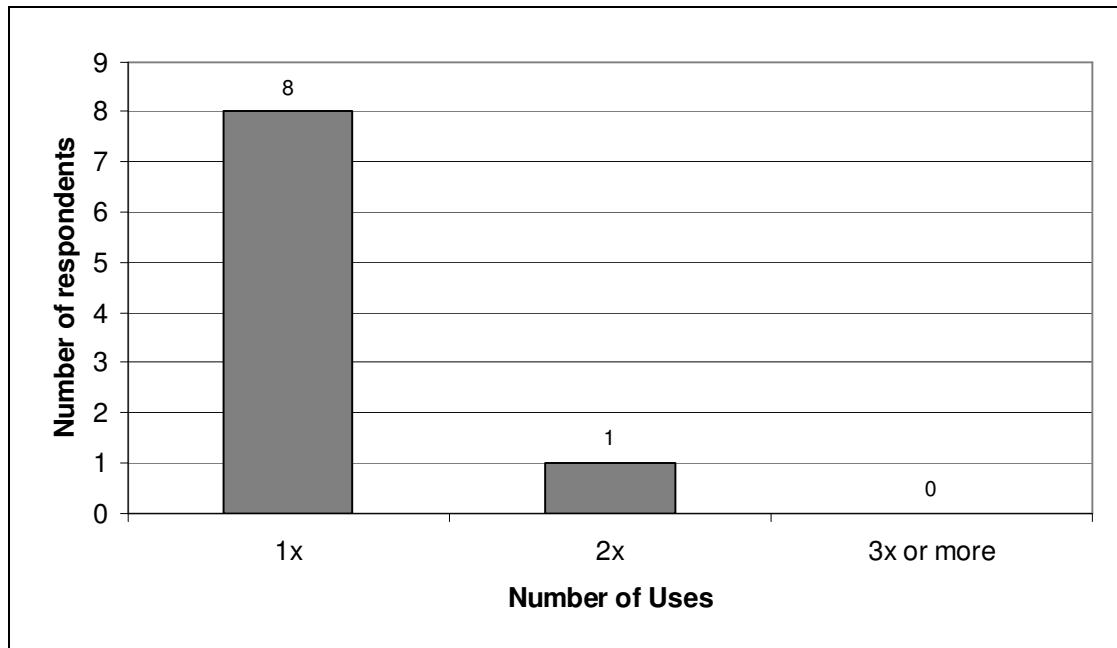


Figure 31: Number of times participant has used an epinephrine auto injector (n = 9)

A physician suggested using an antihistamine to treat a reaction to 84 percent of respondents. In most cases (84%), it was suggested to use an antihistamine before using epinephrine, though eight percent were told to use antihistamines as the primary treatment (Figure 32). An inhaler form of epinephrine was suggested by a physician to only one subject, though using a quick-relief inhaler was suggested to 30 percent of subjects with asthma. When asked what treatments participants had available to them to treat a severe allergic reaction, the top three medications mentioned were antihistamines (90%), epinephrine (86%), and a quick relief inhaler (24%).

The majority of respondents (89%) stated that their health insurance would cover a prescription for epinephrine. Fewer (78%) said that an allergist referral would be covered by insurance. None of the participants had religious reasons for not wanting to use epinephrine or another medication to treat their food allergy.

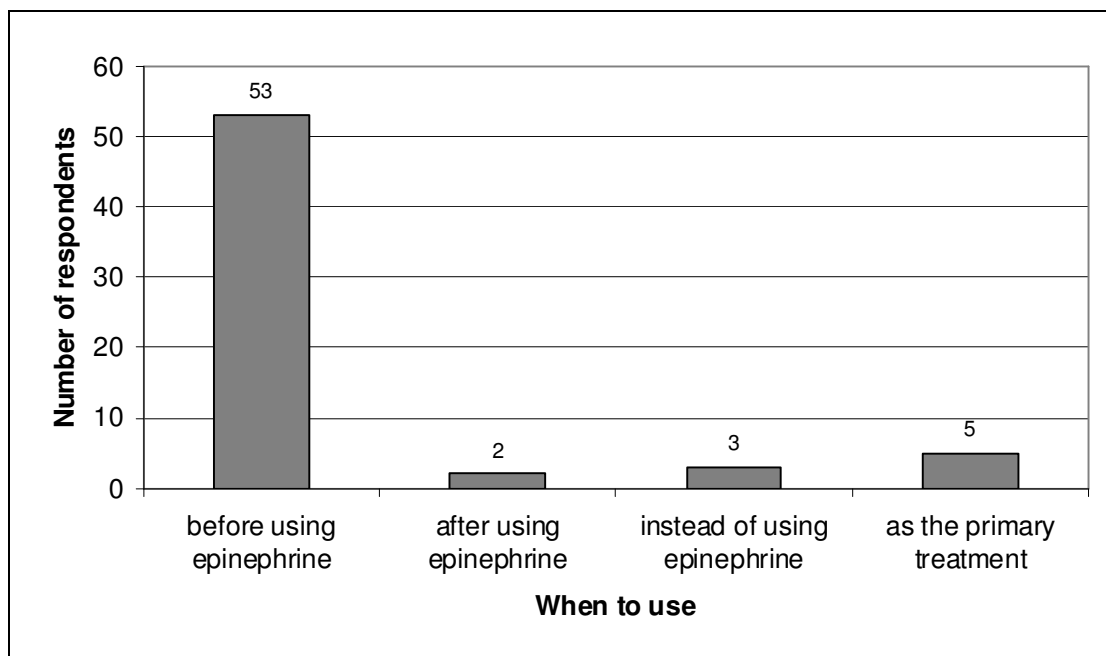


Figure 32: When subjects were told to use antihistamines, if they were told to, by a physician (n = 63, DR = 1, NR = 3)

3.10 EpiPen® training

Of participants who were prescribed an epinephrine auto-injector, the majority (75%) received training on how to use it. An allergist (55%) was most likely to give the instructions, followed by a primary care physician (22%). Most subjects (75%) initially received a verbal explanation with a demonstration, and 36 percent were asked to demonstrate the auto-injector's use. Half of participants (49%) have used an EpiPen® trainer with medical personnel present. Three quarters of subjects (74%) received no specific information on how to store or carry their epinephrine. One auto-injector is most often (76%) carried by the food allergic individual in a purse, briefcase or backpack, with the second most common storage place (25%) being at home in a drawer or cabinet.

The majority of subjects (72%) were able to correctly demonstrate the use of an EpiPen® using the EpiPen® trainer, though this number includes participants who stopped to read the directions before use. The most common mistake in those who demonstrated the procedure incorrectly was failure to remove the cap before use. Participants' confidence in using their epinephrine during a potentially severe reaction spanned the scale, with an average of 7.11, but about 31 percent were not very confident answering a five or below on the confidence scale (Figure 33).

Several factors, including:

- receiving training on how to use an auto injector
- practicing with an EpiPen® trainer
- having a doctor review how to use an auto injector
- being a FAAN member
- being hospitalized or admitted to the ER
- being informed of their allergy by a physician
- consulting an allergist

- and gender of the respondent

had no significant impact on participants' confidence in using an epinephrine auto injector during a potentially severe reaction. Participants were asked open-ended questions about whether any improved education or information would increase confidence using epinephrine or facilitate its use. The most common responses were more training, written instructions, demonstrations, a smaller mechanism, or another form that could be administered without a needle (Tables 8 and 9).

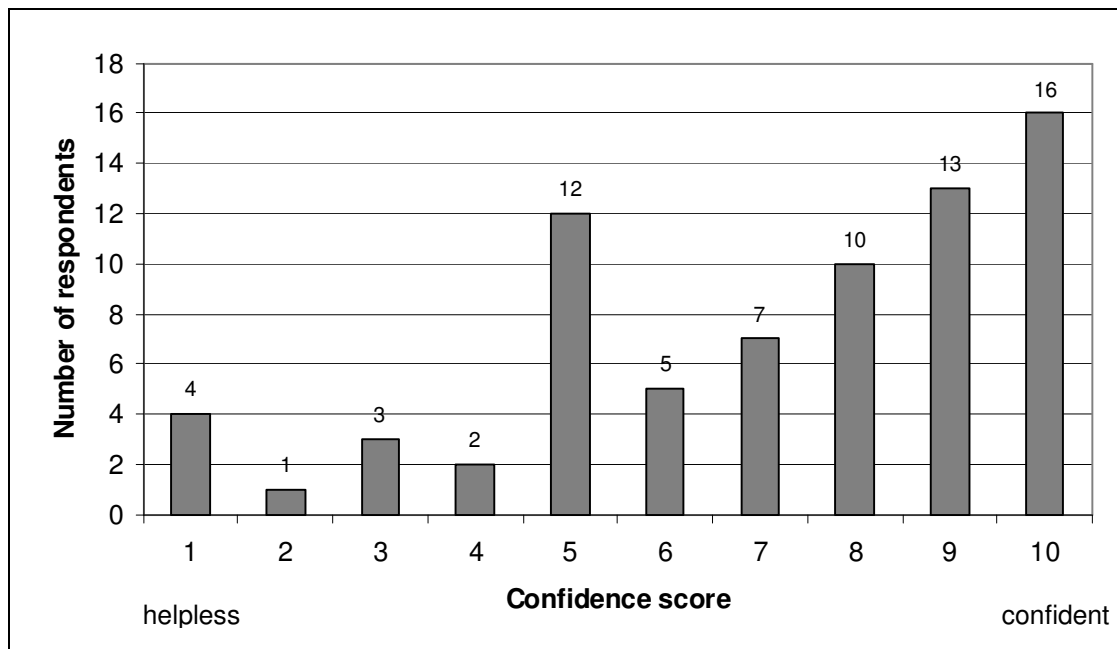


Figure 33: Confidence in using an epinephrine auto injector during a potentially severe reaction (n = 72)

Of the participants who had previously used an epinephrine auto-injector, none said the medical after-effects would discourage them from using it again. One fifth of all subjects with epinephrine prescriptions (21%) said that the pain of the injection would discourage them from using an auto-injector. Only one person said that they preferred not to carry an auto-injector because it is just too frightening to use. Feeling

embarrassed about using an auto-injector discourages four percent of subjects from using it when medically it would be the best option to choose. It is socially awkward for 18 percent of participants to carry an auto-injector. For those who carried epinephrine during adolescence, 38 percent reported that it was especially difficult to carry at that time in their life. Subjects' comfort level with using epinephrine in a social setting ranged the scale, with an average of 7.63 (Figure 34). Seven percent of those who carry an auto-injector reported that they chose to use an antihistamine instead of an epinephrine injection because it felt more socially comfortable.

Table 8: Information would increase participants' confidence in using an epinephrine auto injector* (n = 46, 26 NR)

Improvement	N	Percent
Demonstration of use <ul style="list-style-type: none"> EpiPen® trainer available Explanation from people who have used one Video 	16 5 3 2	34.8
Knowing more about epinephrine <ul style="list-style-type: none"> When to use How to use What it does to your body/side effects Safety of use How it feels to use 	13 4 3 3 2 1	28.3
Reminders from doctors at every visit <ul style="list-style-type: none"> Periodic training Personalized care to alleviate fear 	9 6 1	19.6
Practice with actual auto injector <ul style="list-style-type: none"> Having something to stab expired needles into Having mock body similar to CPR training 	7 4 2	15.2
Knowing what an attack would be like <ul style="list-style-type: none"> How it feels Inducing a reaction with crash team available 	4 3 1	8.7
Information provided for family and friends	1	2.2
Knowing where to find more information	1	2.2

*Some participants had more than one answer

Table 9: Ideas to facilitate epinephrine use* (n = 72, 8 NR)

Ideas to facilitate use	N	Percent
Smaller <ul style="list-style-type: none"> • Pocket size • Size of a lipstick 	23 3 1	31.9
Different form <ul style="list-style-type: none"> • Oral inhaler • Sublingual pill • Liquid • No needle 	19 5 3 3 2	26.4
More training <ul style="list-style-type: none"> • Dry run of how to use • Practice shots • Specifics on use 	17 2 2 1	23.6
More education <ul style="list-style-type: none"> • When to use • Cost/benefit analysis of use • Side effects of use 	12 1 1 1	16.7
Packaging changes <ul style="list-style-type: none"> • Be heat stable to leave in car • Safer • Larger instructions • Color changes (e.g. red as cautionary – “don’t touch”) • Package with Benadryl in carrying case 	6 2 1 1 1 1	8.3
Longer shelf life	4	5.6
Available in public places (e.g. restaurants)	1	1.4

*Some subjects had more than one answer

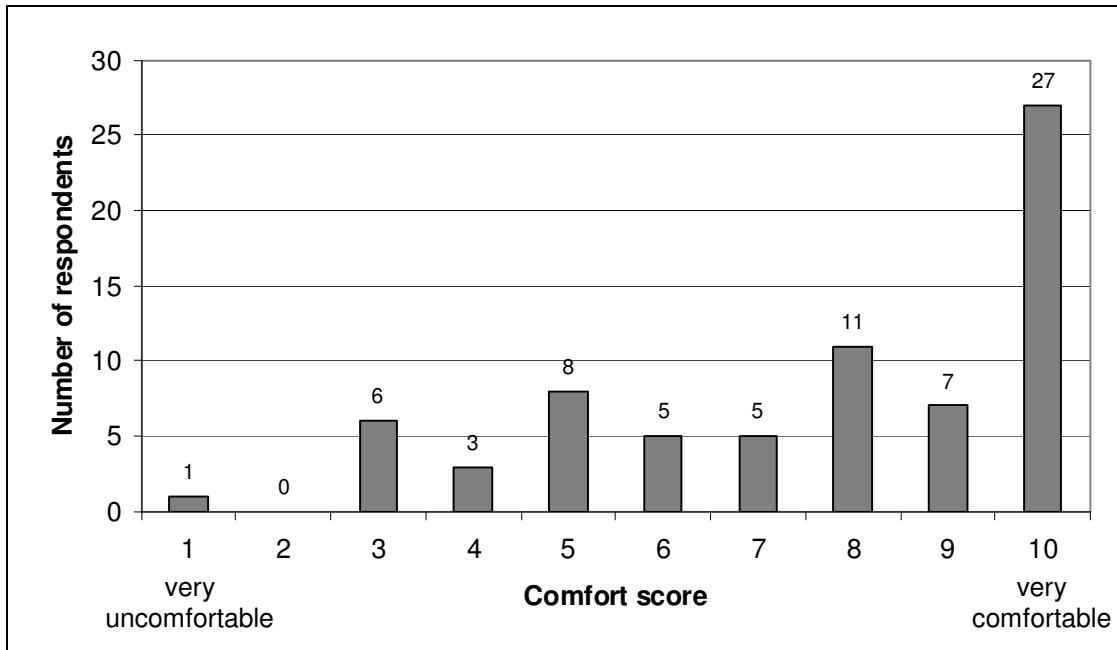


Figure 34: Comfort with use of an epinephrine auto injector in a social setting (n = 72)

3.11 Social Support

The majority of participants (70%) were living with their parents when they first developed their food allergy, while 27 percent were living with a spouse, and three percent were living alone or with friends. At the time they first developed their food allergy, 84 percent of subjects felt comfortable explaining their need to avoid foods and their emergency plan of action, if they had one, to their parents, 87 percent felt comfortable with friends, and 90 percent felt comfortable with their spouse. Currently, 93 percent feel comfortable talking to their parents, 95 percent feel comfortable talking to their friends, 100 percent feel comfortable with their spouse, and 93 percent feel comfortable explaining the need to avoid foods to strangers who would have a reason to know. Most participants had support from parents (87%), friends (79%), and spouse (87%) by changing their food habits at home or when around the food allergic individual. Most study participants felt it was very important

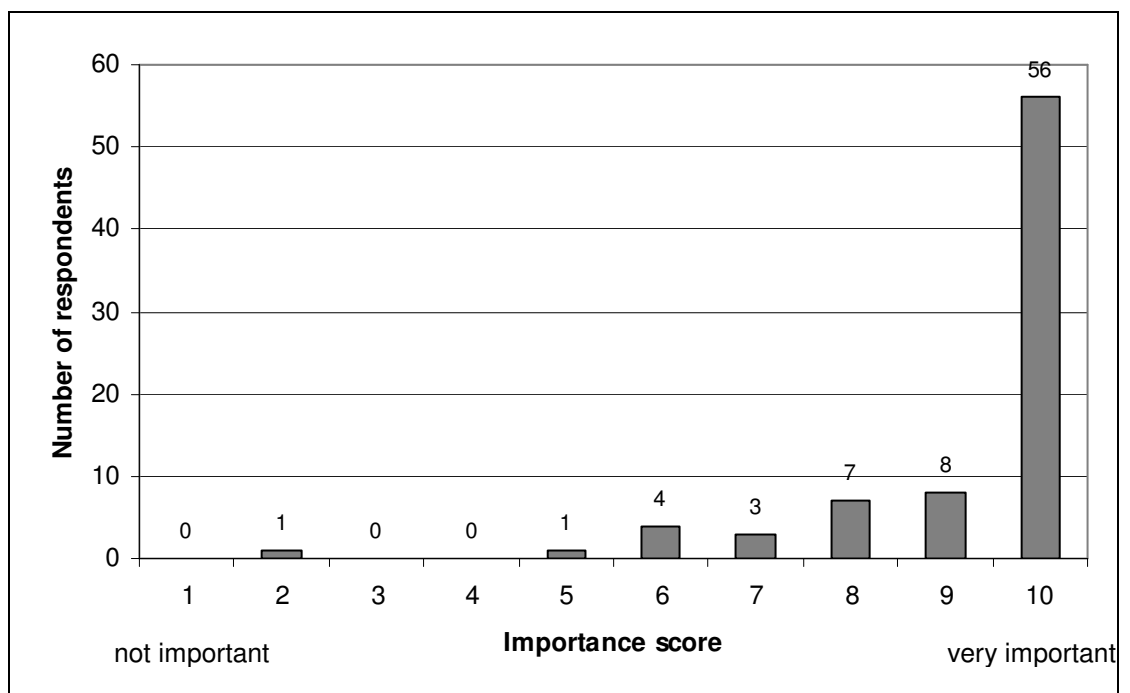


Figure 35: Importance of people closest to participant in regards to food allergy (n = 80)

Table 10: Suggestions on information or processes medical personnel could give participants to help in receiving more support from family and friends* (n = 36, 44 NR)

Suggestion	N	Percent
Written information specific to family and friends <ul style="list-style-type: none"> • Pamphlet • Visual of what happens in the body • List of offending foods 	18 7 4 3	50.0
More education <ul style="list-style-type: none"> • Understand “life threatening” • Understand difference between food allergy and food intolerance • Understand cooking processes/cross contamination • Training on use of EpiPen® 	18 5 3 3 1	50.0
Have family come to doctor’s office	3	8.3
Be given a medical alert bracelet	2	5.6
Electronic database of food allergy information	1	2.8
Video (demonstration of how reaction occurs, e.g. CPR training)	1	2.8

*Some subjects had more than one response

to have the support of people closest to them in managing their food allergy (avg 9.25) (Figure 35). When participants were asked whether there was any information or process that medical personnel could provide that might help them receive more support from family and friends, respondents mentioned written information specific to family and friends and more education about food allergies (Table 10).

CHAPTER 4

DISCUSSION AND CONCLUSIONS

4.1 Findings of interest

The purpose of this study was to assess motivators and barriers to food allergy education and treatment and ascertain severe food allergy sufferers' current knowledge levels and their sources of information. It also was conducted to determine what the participants' considered shortcomings in their food allergy education. The study population included a wide range of persons with severe food allergy, many with allergies to several foods. These subjects were selected for participation in this study because they self-identified with having a life-threatening allergy, as indicated by carrying an epinephrine auto injector or having received emergency care for an allergic reaction, and were pre-screened as previously mentioned. Therefore, it is representative of a population likely to experience severe allergic reactions, and thus a good focus for investigating how food allergy is managed and the factors that affect how confident sufferers are in coping with their allergy.

From the interviews conducted it is apparent that less than half of subjects are receiving specific information from their physicians on how to manage their food allergy. They have not been properly informed when they have experienced a life-threatening allergic reaction, told what symptoms to be aware of, taught how to avoid the foods they are allergic to, or taught how and why their body reacts to specific allergens. Of participants who carry an epinephrine auto injector, only half (49%) have been reminded to renew their prescription annually, and even fewer subjects (33%) were given refresher training on how to use the auto injector. Some participants (25%) were not trained to use the auto injector when they first received it.

Results indicate that although respondents with severe food allergy are confident with the information they have been given by medical personnel, averaging 7.56 on a 10 point scale, they have not been adequately informed about how to avoid the foods they are allergic to (64%), or how to handle a reaction (66%). In addition, confidence in being able to avoid having a reaction outside of the home is significantly lower than that in the home. These data, particularly concerning foods to avoid, indicate a lack of awareness which could result in a higher incidence of accidental ingestion of food allergens. Also, participants are less confident about eating in food service establishments, which could lead to reduced patronage or eating fewer foods.

Sampson, Munoz-Furlong and Sicherer (2006) found that adolescents and young adults felt that more education would make them more confident in handling their food allergy. They also felt that education of their friends and other people close to them would increase their confidence. In interviews of severely food allergic adults in this study, which spanned many age groups (18-78), similar responses to the open ended questions were obtained. When asked what would make them more confident, or what improvements could be made, the majority of participants mentioned more instruction from their physicians about how to manage severe reactions and how to administer emergency medications, such as an epinephrine auto injector. Subjects also mentioned increased education about food allergies in schools and food service establishments as ways to increase their confidence outside of the home.

A study by Kapoor and others (2004) demonstrated that comprehensive education given to families of children with food allergy has been able to increase parental knowledge and decrease the number of food allergic reactions in those children. In this study a team consisting of an allergist, a nutritionist, and a registered nurse can change education levels in a single visit. However, when participants in this study were asked about the confidence they had in their education, and how

knowledgeable they felt about food allergy, there was no statistical increase in confidence or knowledge demonstrated by those who had received such information from medical personnel. This finding demonstrates that although subjects want an increase in information, those who have been given information are no more confident than those who have not. In fact, subjects who looked up information on their own felt more knowledgeable about understanding why their body reacts to certain foods. This discrepancy could be due to this study using a rating system for confidence and knowledge, while the study by Kapoor and others used a questionnaire specifically designed to determine amount of knowledge. If NY/NJ respondents were asked specific questions about their knowledge of food allergy there might be a difference between those who have received information and those who have not.

Although there was no significant increase in confidence in education about food allergy and how the body reacts, being educated about cross contamination and how to read labels on food packages does increase participants' confidence in being able to avoid foods they are allergic to and avoid having severe reactions both at home and away from home. In addition, having a physician inform the participant that they did have a severe food allergy, increased their confidence in using their plan of action and avoiding having a severe reaction at home.

Another motivating factor that increased respondents' confidence in avoiding reactions was being a member of a support group, such as FAAN. Membership in a support group also increased how often an epinephrine auto injector was carried. As an injection of epinephrine is the only method to treat a life threatening allergic reaction, greater publicity about or by such groups concerning auto injectors use may be able to prevent a greater number of severe reactions that require emergency care. Those participants who have been hospitalized, or admitted to the ER, are currently more confident in using their plan of action than those who have not. This could

indicate that experiencing and surviving a severe reaction increases confidence because the plan of action has been shown to be effective. Several participants suggested that experiencing a reaction or using an epinephrine auto injector would make them feel more confident, which would corroborate this assumption.

4.2 Bi-coastal comparison with UC Davis collaborative study

There were many similarities between the results found by project collaborators Phillip and Bruhn (2007), who interviewed 65 food allergic volunteers in California (CA), and those found in this study conducted in New York and New Jersey (NY/NJ), though there were also differences in the two populations. Demographic information, such as number of males and females, ethnicities and family history of food allergy was very similar. The NY/NJ study did have a larger number of subjects who were members of FAAN (29% in NY/NJ, 5% CA), which is most likely due to using their listserv as a method of recruitment. Also, the majority of FAAN members are in the east. There was a greater predominance of shellfish as the allergen responsible for participants' first reaction in the NY/NJ study, and approximately one quarter more of NY/NJ participants were allergic to more than one food, but other allergenic food occurrences were similar. Triggers of allergic reactions, such as breathing in cooking vapors or kissing an individual who has previously ingested the food and symptoms displayed during the reaction were also comparable between groups.

When asked to recall the most severe reactions participants could clearly remember, a greater number of NY/NJ subjects sought emergency care, though their rankings of concern and severity of reaction, as well as the additional descriptors used were similar. Their interaction with medical personnel is also analogous. Comparable numbers of participants have been informed by a doctor that they have a food allergy,

with slightly higher percentages in NY/NJ having subsequent (94% in NY/NJ, 81% in CA) and current (95% in NY/NJ, 92% in CA) primary care doctors are aware of their allergy. In addition, a greater number of NY/NJ subjects (65% in NY/NJ, 41% in CA) were encouraged to make a follow-up appointment after their reaction requiring emergency treatment.

When questioned about information received from medical personnel 20 percent more of NY/NJ respondents (54%) had been given information about symptoms with which to be concerned, as well as 25 percent more (44%) having been given information to understand food allergy and how and why the body reacts. Despite the greater number of participants in NY/NJ being supplied with food allergy information, nearly identical percentages of respondents in both groups (75% in NY/NJ, 77% in CA) sought and looked up information on their own. Almost twice as many NY/NJ subjects (90%) felt they used the information they had received or looked up in their daily life.

As with the discrepancy between populations in information received from medical personnel about symptoms and reactions, approximately one third more of NY/NJ participants (95%) were told to avoid the food they were allergic to by a physician. Greater numbers were also told how to avoid the food (36% in NY/NJ, 18% in CA) and how to read labels on food packages (30% in NY/NJ, 14% in CA). In addition, more NY/NJ participants were shown a list of possible food ingredients that pertained to their specific allergen (24% in NY/NJ, 7% in CA). Despite the numbers being higher in the NY/NJ subjects, still barely a third of respondents have been given information to help them in avoiding specific food allergens, making the availability of this material deficient across both populations.

In terms of their comfort levels about the ability to avoid allergenic foods in restaurants, both populations were similar. The majority of participants (94%) has

heard of cross contamination and most have had a reaction in a restaurant (80%). Confidence was significantly higher in ability to avoid foods at home in comparison to away from home in both groups, and participants were more confident in the information about avoiding foods and their knowledge about it. Comfort level in discussing food allergy needs with food service personnel spans the scale in both studies. Both groups also had similar suggestions for how to improve education and explanations regarding food avoidance. They suggested programs be developed and delivered to school personnel, fellow students and all restaurant employees.

Approximately twice as many participants in NY/NJ received a plan of action from medical personnel (34%), though it was barely a third of participants. Twice as many also referred to calling 911 or going to the ER (99%) or using epinephrine (68%) as part of their plan of action. The number of participants who include antihistamines (68% in NY/NJ, 66% in CA) in their prescribed or self-developed plan was almost identical. More than 20 percent fewer of NY/NJ subjects (66% in NY/NJ, 88% in CA) have used their plan of action during a severe reaction.

Antihistamines were recommended as a method to treat food allergic reactions to nearly 30 percent more of the NY/NJ population (84%) than CA (57%), though many fewer in NY/NJ (8%), than CA (64%) were told to use the antihistamine as their primary method of treatment during any reaction. An inhaler form of epinephrine has not been recommended to the majority of participants in either population. Comparable numbers of subjects with asthma (30% in NY/NJ, 20% in CA) have been told to use their quick relief inhaler as part of the food allergic reaction treatment.

Participants with epinephrine auto injectors have received them through similar methods, with most being prescribed by a physician at a follow-up appointment after a severe allergic reaction. Most subjects had either one or two auto injectors prescribed at a time, though almost a quarter more of the participants in NY/NJ had their

prescriptions refilled every year (74%). Similar numbers of participants fall into the categories of how often an auto injector was carried, with only approximately half carrying one at all times. For participants who did not carry an auto injector, all of their physicians were aware of their food allergy, though 25 percent more of the NY/NJ population knew why they were not given an epinephrine prescription (75%).

Three quarters of the NY/NJ population has been given training on how to use an epinephrine auto injector, while only 58 percent of the California population has. In addition, almost twice as many of the NY/NJ respondents have had the opportunity to practice with an EpiPen[®] trainer with medical personnel present, though fewer of them have received instruction on where to store or carry their auto injector. More of NY/NJ subjects were correctly able to demonstrate how to use an auto injector as well. Comfort level of using an auto injector in a social setting was similar in both groups (avg 7.63).

Both populations felt similarly about social support in regards to their food allergy from family and friends. The most common living situation in both groups of subjects when they developed their food allergy was living with their parents. The majority of participants in both groups felt that having support from people closest to them was very important.

Overall, the NY/NJ study had higher percentages of people who had received education from medical personnel about symptoms, how the body reacts and how to avoid the foods to which they were allergic. Despite the higher percentages, education appears to be deficient on both coasts, with less than half of participants receiving specific information about their food allergy. Also, both populations stressed the need for additional education from medical personnel for themselves, as well as education for the general public and food service personnel. They further agreed on

improvements to increase the use of epinephrine auto injectors, such as alternate forms and smaller packaging, in addition to more education and training.

4.3 Study Limitations

There were a number of limitations to this study. The original goal of the study was to interview 100 volunteers, though due to difficulties in recruiting only 80 useable interviews were conducted. Although this number was large enough to have statistical significance, a larger sample would have been desirable.

Participants were asked to self-report reactions and interactions with medical personnel. As many reactions had happened several years ago, it is possible that the symptoms and education received may have been misremembered or forgotten. In addition, all ratings were on scales from one to ten, but scales were not standardized between participants. Thus averages of scores could be skewed due to subjects' avoidance of the ends of scales, or higher or lower tolerances to pain. It is also difficult to quantify answers to open-ended questions, as all respondents may not have interpreted the question the same way. When a response appeared to more appropriately answer a question posed later in the survey, it was moved to maintain consistency.

Another possible limitation is that part of the group studied may be more knowledgeable about food allergy than the average food allergic consumer. Participants were recruited through food allergy listservs and support groups which may supply more information than that available to those not a member of such groups. Also, stories about food allergy were run predominately in large cities where patients may have greater access to food allergy education than their rural counterparts. However, since the number of participants who received education was low in the NY/NJ population, it emphasizes the fact that people with less information

about food allergy may be at greater risk for more severe reactions. Although we did not exhaustively evaluate participants to verify their food allergy, the reported foods, symptoms, repeated reactions and possession of epinephrine auto injectors indicate that subjects likely had severe, life threatening food allergies.

4.4 Overall Conclusions

Both locations of this study have demonstrated that there are many areas where current food allergy education falls short. Medical personnel should be the best resource for severe food allergy sufferers, yet less than half of participants are receiving any information from doctors about symptoms with which to be concerned, about how to handle severe allergic reactions, or about how to avoid the foods to which they are allergic. In subjects who carry epinephrine auto injectors, barely a third are reminded of the importance of renewing their prescription and even fewer have had their physicians review how to use an auto injector so they would feel more confident and comfortable using it. As physicians are the only resource available to instill the magnitude of the impact epinephrine has on preventing death it is imperative that they thoroughly educate all of their patients on this important issue. Many respondents stated that one of the most helpful things they had learned from their physicians was information about the severity of their allergy. If medical personnel took a more active role in informing their patients about the possible consequences of ingesting the allergen or of not being prepared for a reaction, they could be instrumental in reducing the number of emergency room visits and hospitalizations.

In addition to providing more information to their patients about food allergies in general, it is also important for physicians to better instruct patients in the use of epinephrine auto injectors. Patients should be educated when they first receive the prescription through the use of written instructions and a demonstration. Written

instructions should highlight the necessity of renewing the prescription every year, possible side effects, and storage instructions. Physicians need to comprehend the importance of annual appointments to discuss their patients' allergies and to verify proper allergy management.

Patients want information from physicians that is clearer and that outlines the reasons they have allergies, the symptoms and consequences of an allergic reaction, a plan of action, and ways to successfully avoid their allergens. They want this material in written form, as verbal information can often be forgotten or remembered incorrectly, especially if the patient is still experiencing or recovering from a reaction. This information should detail the foods that can trigger a reaction, the steps that should be taken in an emergency situation, the possible evolution of an allergy, including developing additional allergies later in life, and how to be alert for their allergic food(s) in packaged foods and at restaurants.

As food allergy sufferers can only take a portion of the responsibility for watching what they eat in public places, so it is essential to institute better education of the general public, especially food service personnel. Participants expressed a great desire to see more educational programs implemented in schools and food service establishments. People need to be made aware of the differences between food allergies, food intolerances and food preferences, and the severity of each. Many respondents expressed concern at their past interactions in restaurants, demonstrating that those establishments should develop a procedure both in the kitchen as well as in the front of the house on how to handle food allergic consumers. Having the support of people around them can help food allergy sufferers feel more comfortable when eating outside the home.

4.5 Suggestions for future research

This study explored the current feelings of confidence and knowledge held by volunteers with severe food allergy, as well as their motivators and barriers to following appropriate measures to manage their allergy. To better understand the influence that information provided by medical personnel has on patients' confidence and knowledge scores, participants should be interviewed a second time, after receiving the information they indicated would be helpful in increasing their confidence. Comparing the two scores would allow researchers to determine what type of information is most helpful in increasing patients' feelings of confidence, comfort and knowledge. A follow-up study should also target a wider geographical area and more participants. The current study had a wide variety of ages and food allergens, but was limited by the location of the research institutions. By interviewing subjects in urban, suburban and rural areas, and comparing their confidence and knowledge levels, the locations that have the greatest need for additional education can be determined.

Future research should also investigate the effect of food allergy onset age on confidence levels and knowledge to ascertain whether subjects become more knowledgeable and confident over time, or whether they become more lax in managing their allergy as time goes on. Understanding the factors that influence food allergy management would assist in developing appropriate educational materials and implementing educational programs.

Given the importance that participants place on the need for additional education for themselves, physicians, food service personnel and the general public, more research is needed to establish the current levels of knowledge as well as the best method to educate individual groups. Possible research could include development of food allergy education programs in school health classes, parental education in parent

teacher associations, continuing food allergy specific education for general practitioners, or incorporation of food allergy training in food service establishments.

APPENDIX A
MAILER QUESTIONNAIRE

Code number _____

Date _____

☐ Male ☐ Female

MAIL QUESTIONNAIRE

Multifaceted Food Allergy Education Program Cornell University

Your response to these questions will help us better understand your food allergy.

1. What is your age in years _____?
2. With what ethnic group do you identify? Please check appropriate box.
 - ☐ African- American/Black
 - ☐ Asian
 - ☐ Caucasian
 - ☐ Latino/Latina Hispanic
 - ☐ Native American (American Indian)
 - ☐ Multi-ethnic (check all that apply)
3. How old were you when you first noticed you had a food allergy or that your parents noticed you had a food allergy? _____ Years
 - What was the food? _____
 - What were your reactions to the food? _____
 - _____
 - _____
 - _____
4. How many minutes after eating the food does the reaction start? _____ minutes.
5. What is the very first sensation of a reaction starting? _____
- _____
- _____
- _____
6. Do you have additional food allergies? ☐ Yes ☐ No

If yes, how old were you when you or your parents first noticed this food allergy?
_____ years.

What was the food?

1. _____
2. _____
3. _____
4. _____
5. _____

Was the first reaction to each food the first known exposure? Or was this a previously tolerated food?

- | | | |
|----|--------------------------------|--|
| 1. | <input type="checkbox"/> First | <input type="checkbox"/> Previously tolerated food |
| 2. | <input type="checkbox"/> First | <input type="checkbox"/> Previously tolerated food |
| 3. | <input type="checkbox"/> First | <input type="checkbox"/> Previously tolerated food |
| 4. | <input type="checkbox"/> First | <input type="checkbox"/> Previously tolerated food |
| 5. | <input type="checkbox"/> First | <input type="checkbox"/> Previously tolerated food |

What was/were your reactions to the food(s)?

1. _____
2. _____
3. _____
4. _____
5. _____

7. Does your reactivity depend on whether the food is raw or cooked?

☐ Yes ☐ No

If yes, what causes the more severe reaction?

☐ Raw ☐ Cooked

8. Have you ever had a reaction by touching the food?

☐ Yes ☐ No

If yes, please describe the circumstances

and the reaction. _____

9. Have you ever had an allergic reaction from being kissed? ☐ Yes ☐ No

If yes, please describe the circumstances (when, how long after eating, tooth brushing?, cheek, lips, oral mucosa; was the partner aware of your food allergy, what was the reaction)_____

10. Were you ever hospitalized for a food allergy reaction? ☐ Yes ☐ No

When? _____

How many times? _____

What treatments were you given?_____

11. If yes, were you intubated? ☐ Yes ☐ No

12. Did you receive a prescription for EpiPens when you were discharged?

☐ Yes ☐ No

If not, why not? _____

13. Were you ever treated in an emergency department? ☐ Yes ☐ No

When? _____

How many times? _____

What treatments were you given?_____

14. Has a physician ever told you that you had a food allergy? ☐ Yes ☐ No

What kind of physician was the first to discuss your food allergy with you or your family? _____

Have all of your subsequent primary care doctors been aware of your allergy?

☐ Yes ☐ No

Have any doctors ever downplayed your allergy? . ☐ Yes ☐ No

What do you recall about that? _____

15. Is your current primary care physician aware of your food allergy? .

. ☐ Yes ☐ No

16. Has an allergist been consulted for any of your allergy problems? .

. ☐ Yes ☐ No

What conditions did the allergist help you with? _____

If the food allergy was addressed, what type of evaluation or testing was performed? _____

If you had skin testing to foods, was it tolerated or did you have a systemic reaction to the testing? _____

If your food allergy was NOT addressed by the allergist, why do you think this slipped through the cracks? _____

17. What foods are avoided either due to allergy or concern over cross-reactivity?

18. Do you wear a medical alert bracelet?

☐ Yes ☐ No

Why or why not? _____

Has a doctor ever recommended this to you? ☐ Yes ☐ No

If yes, how many years ago was one recommended to you? _____ years.

19. Are you a member of the Food Allergy and Anaphylaxis Network? ☐ Yes ☐ No
If yes, how old were you when you joined? _____ years.

20. Do you have any of the following or did you have as a child?

- Asthma
☐ Child only ☐ Child and now ☐ Now, but not as a child
- Insect Sting Allergy: (to what _____)
☐ Child only ☐ Child and now ☐ Now, but not as a child
- Red itchy skin (Atopic Dermatitis) or Allergic Eczema
☐ Child only ☐ Child and now ☐ Now, but not as a child
- Hay Fever or stuffy nose and itchy eyes due to allergies (Allergic Rhinitis)
☐ Child only ☐ Child and now ☐ Now, but not as a child
- Drug allergy (to what _____)
☐ Child only ☐ Child and now ☐ Now, but not as a child

21. If you have asthma:

Have you ever been hospitalized for asthma not related to a food reaction?
☐ Yes ☐ No

Have you ever been to an emergency department for asthma not related to a food reaction? ☐ Yes ☐ No

What medication are you on for your asthma? _____

22. If you have, or had, red itchy skin (atopic dermatitis):

Were there any foods that exacerbated the skin condition? _____

23. If you have stuffy nose and/or itchy eyes due to allergies (allergic rhinitis or allergic conjunctivitis):

What medications do you take for this condition? _____

Have you ever had allergy shots or immunotherapy, also called allergy vaccines?
☐ Yes ☐ No

24. Is there a family history of food allergy? ☐ Yes ☐ No

Please list the food (s) they are allergic to:

Mother: _____

Father: _____

Siblings: _____

Children: _____

Other: list _____

**THANKS so much! Please bring this form to the
interview**

APPENDIX B
PARTICIPANT INFORMED CONSENT FORM

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Conducted by

CORNELL UNIVERSITY & THE UNIVERSITY OF CALIFORNIA, DAVIS

Title of the Study: Multifaceted Food Allergy Education Program

**Investigator's Name: Robert B. Gravani, Ph.D., Department of Food Science
Cornell University 607-255-3262**

PURPOSE

You are being asked to participate in a research study. We hope to better understand how people manage their food allergies. We plan to improve the information available to physicians and patients as a result of what we learn in this study.

PROCEDURES

If you decide to volunteer, you will be asked to describe the nature of your food allergies, how the allergy affects you, and how you deal with it. This interview will take about one to one and a half hours. It will be scheduled in your community at a time of mutual convenience. We would also like to contact you again in a year to ask how you are managing your allergy. You were also sent a questionnaire in the mail. It should take less than 30 minutes to complete this questionnaire. We will collect it at the start of the interview.

RISKS

There are no risks to you for your participation in this study other than those encountered in day-to-day life.

BENEFITS

It is possible that you will not benefit directly by participating in this study. If you wish, we will provide (without charge) information on food allergies developed through the study.

CONFIDENTIALITY

We will not associate your name with any information collected. Information you provide will be coded as a random number, not by name. We will keep your name and contact information on a separate sheet of paper so we can contact you again to see if the educational material we provide is useful. We will record all answers using the random number. When the project is completed, the list associating names with numbers will be destroyed. Your responses to questions will be tape recorded as a check that we enter information correctly. The audio-tape will be checked by a graduate student, medical assistant or clerical person. Again, the tape will refer to interview numbers, not names.

COSTS/COMPENSATION

There is no cost to you beyond the time and effort required to complete the interview. As a token of appreciation for your participation in this study, we will provide you with \$25 in cash at the conclusion of your interview.

PARTICIPATION IS VOLUNTARY

Taking part in this study is completely voluntary. You may skip any questions that you do not want to answer. If you decide not to take part or to skip some of the questions, it will not affect your current or future relationship with Cornell University. If you decide to take part, you may change your mind about being in the study and quit after the study has started.

QUESTIONS

If you have any questions about this research project please contact Robert B. Gravani at 607-255-3262. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the University Institutional Review Board for Human Participants (IRB) at 607-255-5138 or access their website at <http://www.irb.cornell.edu>.

YOUR SIGNATURE, BELOW, WILL INDICATE THAT YOU HAVE DECIDED TO VOLUNTEER AS A RESEARCH SUBJECT AND THAT YOU HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED ABOVE. YOU WILL BE GIVEN A SIGNED AND DATED COPY OF THIS FORM, AS WELL AS THE LETTER TO RESEARCH PARTICIPANTS.

Signature of participant or legal representative _____

Date _____

Signature of Investigator _____

Date _____

This consent form will be kept by the researcher for at least three years beyond the end of the study and was approved by the IRB on January 29, 2008.

APPENDIX C
ORAL QUESTIONNAIRE

Interviewer: *Thank you for taking the time to participate in our study. We are doing this study so that we can learn from people who have food allergies ways that they have managed living with their food allergies day to day, and what kind of help they may have received from their physicians and other medical personnel. With this information, the goal of our research is to improve education being given to people with food allergies by doctors and other medical personnel, as well as the general public.*

The questionnaire generally takes about 1 hour. I will be asking you questions about your reactions, medications you MAY have used and what sort of advice you MAY have received from medical personnel along the way. There is no right or wrong answer to ANY of these questions. We have spoken to hundreds of people with food allergies and all of their experiences are unique (different). I also understand that some reactions you may have had years before. It is OK to just answer to the best of your recollection. We will also be using scales (show them a scale) which are ranked 1-10. The scales are used with questions that are asking you how you felt about something such as an allergic reaction you have had or medical education you may have received. Choosing a rating will help us enter the information accurately into our database. Thank you so much! We really appreciate you taking the time to help others who also have food allergies.

I also wanted to ask you again if you would mind us taping the interview. We will be using the recording to verify the information entered is correct. Thanks!!

Multifaceted Food Allergy Education Program Patient Questionnaire

Date of Interview: _____

1. To the best of your recollection, please recall one of your earliest , worst reactions **(that you can clearly remember)** in which it was necessary for you to have emergency treatment, *if you have had emergency treatment, otherwise, your worst reaction that you clearly recall*

swelling of face	swelling of other areas of the body	
redness of skin, flushing	hives	nasal congestion
itching	itchy eyes	itchy throat
throat swelling	difficulty speaking	squeaky voice
coughing	wheezing	tightness in chest
shortness of breath	nausea	vomiting
diarrhea	abdominal cramps/pain	light-headedness
passing out	sense of doom	fear
palpitations	unusually fast heartbeat	other _____

(later use only: severity code assigned: _____)

2. Did you go to the **ER** **Hospital** **Physician's Office** **Other** _____

3. At what age did this occur? _____

4. **SCALE Perception:** (1-calm, 10- fearful) using the scale;
Please rank how concerned you felt about your reaction _____

5. Please describe your feeling. _____

6. **SCALE: Severity** of Reaction: (1- very mild, 10- very severe) using the scale;
Please indicate the severity of your reactions **as YOU perceived them** _____

Emergency Treatment *Some people have had medical treatment for their reactions, others haven't. I am going to ask a series of questions now that may or may not apply to your situation.*

7. **If you received emergency treatment immediately following your reaction:**

Please describe the treatment you were given at the ER, Hospital, etc. (then skip to Q11)

N/A Can't remember the type of treatment given

8. **If you did not seek emergency treatment immediately following your reaction**

What treatment did you use for your reaction *if any*? _____

9. Did you follow up with a visit to either your primary care physician or allergist ***specifically to discuss this reaction?***

Yes (skip to Q11)

No, did not follow up

10. If you did not visit your physician after your reaction, did you ever tell them about your reaction? *We ask this because we think many doctors don't think about asking about food or insect allergies – they ALWAYS ask for DRUG allergies -- and if a reaction happened a long time ago, people may not think of telling their doctors either. We will ask this sort of question in several ways as the interview continues*

Yes

No

No, already familiar with the reaction

Please elaborate on both yes and no answers:

Communication at Emergency visit

(If they have ever had emergency care immediately following a reaction, if NOT, skip to Question 25)

Now I am going to ask some questions about how your doctor or nurse communicated with you when you had a reaction requiring emergency care – sometimes people are given a lot of information, other times, none. Also, some people are given instructions on what to do if a reaction occurs again, some are not. Some people with food allergy are given prescriptions for EpiPens or “Bee sting kits” to use, some are not. It is totally fine if these questions don’t apply to you.

11. Think of a reaction in which you clearly remember the care you received by medical personnel.

Did you receive your emergency care at the:

ER **Primary Care** **Physician’s office** **Urgent Care** **Other**__

12. Were you informed by medical personnel that this was a life-threatening allergic reaction?

Yes **No**

13. Please describe what you were told.

14. **SCALE: Severity** of Reaction: (1- very mild, not life threatening to 10- very severe, life threatening):

Please rank what the doctor or nurse told you about your reaction _____

Not informed

15. Were you encouraged to make a follow up appointment with your: **Primary Care Physician** or an **Allergist** to discuss your reaction and a future course of action?

Yes **No (skip to 19)**

16. Did you have a follow up appointment with either of them?

Yes (skip to Q18) **No**

17. If **no**, why not? (then go to Q19) _____

18. If **yes**, did you discuss your food allergy with them? (**then go to Q21**)

Yes **No**

19. If you **did not** have a follow up appointment with your physician or an allergist immediately after, did you **ever** inform either one of them that you had a severe allergy?

Yes (skip to Q21) **No**

20. If **no**, why not? _____

Epinephrine and other medications

Now I am going to ask more about medicines that are given to SOME people with food allergies. This does not mean that any of these medications are indicated for your situation, so it is OK if it does not apply to you. You will notice many questions about EpiPens, which are a type of self-injectable adrenalin, previously known in a different form as “bee sting kits”. If you had one at one time, but not now, or never had one, that is fine. We are trying to find out why people do or don’t carry them.

Emergency Visit (Both EpiPen and non EpiPen users)

21. At your emergency visit, did you receive an EpiPen prescription from medical personnel? **Yes** **No (skip to Q24)**
22. Did you have the **prescription filled**? **Yes (skip to Q29)** **No**
23. If **no**, why not? _____
24. If you **did not** receive an epinephrine or adrenalin prescription during your emergency visit, were you **encouraged to request an EpiPen prescription** at a follow up visit with your primary physician or allergist?
 Yes **No**
25. If you had a **follow up visit** with your Physician or Allergist, did you **receive an EpiPen prescription** from them? **Yes** **No (skip to Q27)**
26. If **yes**, did you have this prescription filled? **Yes (skip to Q29)** **No**
27. If you have never been prescribed an EpiPen, have you **ever** requested an EpiPen prescription from your physician? **Yes** **No (skip to Q38)**
28. If **yes**, what was the reason given for not writing a prescription for you? (**then go to Q38**)

29. How many EpiPens were you prescribed? **One** **Two** **Three**
30. Do you have your **prescription refilled** every year? **Yes** **No**
31. Do you use a **medical website** service to inform you when you need to refill your EpiPen prescription? **Yes** **No**
32. Have you ever heard of this medical website service? **Yes** **No**
33. Do you **carry your EpiPen** with you: **at all times** **sometimes**
 only at certain times **never carry it**

34. Do you have it with you right **now**? **Yes** **No**
35. If you do **not carry** your epinephrine with you at all times, can you tell us why?

36. Have you ever used your EpiPen during a reaction?
 Yes **No (skip to Q44)**
37. If **yes**, how many times? (**skip to Q44**) _____
38. ***Preamble: Since you did not receive an EpiPen prescription, I am going to ask more questions about that because some people are not given them for specific medical reasons, or other reasons depending on the type of reaction they had. We are just trying to find out if this issue was discussed.***
38. If you **did not** receive an EpiPen prescription from your physician, Do you know why?
 Yes **No (skip to 40)**
39. If **yes**, why? _____
40. Are you on beta-blocker medication? **Yes** **No**
41. Was the EpiPen discussed but another medication given? **Yes** **No, nothing was given or discussed (skip to Q43)**
42. If **yes**, do you know why? _____

43. Was your physician aware that you had that reaction to food that you told me about?

Questions regarding other medications:

Again, it is possible that none of these questions will apply, but sometimes people are advised by a physician to use medicines if they have a reaction again, other times people just devise treatments themselves. We are interested here if your doctor made specific suggestions for medicines to use.

Benedryl/ other antihistamines/ other meds:

44. Did your physician suggest you use diphenhydramine (Benedryl) or another antihistamine to treat your reaction? **Yes** **No (skip to 46)**

45. If yes, in what situation?

 Before using your epinephrine?

 After epinephrine?

 Instead of epinephrine?

 As the primary treatment, epinephrine was never discussed

46. Did your physician suggest you use an inhaler form of epinephrine?

Yes **No**

47. If you have asthma, did your physician suggest that you use your quick-reliever inhaler as part of your food allergy treatment (usually this is albuterol)?

Yes **No** **Don't have asthma**

Now, I want to know all of the medicines you are using for a reaction. It doesn't matter if it was suggested by a doctor, or you developed the approach yourself based on your experience

48. What medications or approaches are you currently using to treat your reactions?

The following questions only apply if they use Epi – if not, skip to question 70

The following questions only apply if they use Epi – if not, skip to question 70
EpiPen Training
If they received a prescription for EpiPen

49. Did you receive **training** on how to **use** your EpiPen?

Yes **No (skip to Q53)**

50. Who taught you?

Physician: Primary Care

Physician: Allergist

Not a person: a video

Pharmacist

Friend

Physician: Emergency Department

Nurse

Not a person: a written information-pamphlet

Family member

Other_____

51. How were you taught?

Verbal explanation only

Verbal explanation with a demonstration

Verbal explanation, demonstration, and then I had to demonstrate it back

Watched a video

Read a pamphlet

52. During your training, did you **practice with an EpiPen trainer** with medical personnel present?

Yes **No**

53. How were you taught to **store or carry** your EpiPen?

refrigerator

not in glove compartment

in a pocket carrier

Other: _____

NOT in refrigerator

in purse or briefcase

No specific teaching

54. Where do you store or carry your EpiPen? _____

55. Can you **show me** how you were taught to use your EpiPen with this EpiPen trainer? (have EpiPen trainer available)_____

56. **SCALE: Confidence:** (1-helpless, 10-confident), after you were taught (or not) how to use your EpiPen, how comfortable did you feel about using the EpiPen during a potentially severe reaction? _____

57. Can you think of any improved education or information that would increase your confidence using the EpiPen? _____

EpiPen Support/Barriers

Now I am going to ask questions related to whether you are currently getting support from your primary care doctor or allergist regarding your food allergy.

58. Is your current doctor (Primary Care Physician or Allergist) aware that you have a severe food allergy that requires the use of epinephrine or other medications to treat your reaction?

Yes No

59. If you carry EpiPens, does your Primary Care Physician or Allergist discuss with you the need to renew your EpiPen prescription every year?

Yes No

60. Does he/she review with you how to use your EpiPen so that you would feel confident and comfortable using it in an emergency situation?

Yes No

I am now going to ask you a series of questions about issues that have come up in previous interviews. They may not all apply to you. These questions have to do with EpiPens, which as we have discussed, are recommended for some people with food allergy and are a dose of adrenalin given by self-injection in the thigh. We are trying to find out if there are barriers to some people not using EpiPens for whom they may have been recommended. If medical personnel have never recommended an EpiPen for you, I will be skipping most of these questions. If one has been recommend at some time, or if you carried one for a while, then stopped, I will be asking you these questions even though you don't have one now.

61. If you have used an EpiPen, do the medical after-effects of the EpiPen discourage you from using it? Eg: increased heart rate, anxiety, weakness, diarrhea, and nausea.

Yes No N/A

62. If yes, which effects bothered you? _____

63. Would the pain of the injection of an EpiPen discourage you from using one?

Yes No

64. Do you prefer not to carry an EpiPen because it is just too frightening to use?

Yes N/A– I carry one N/A

65. Does feeling embarrassed about using your EpiPen discourage you from using it when medically you know it would be the best medical option for you to choose?

Yes No, I use it anyway N/A

66. Is it awkward socially for you to carry your EpiPen with you?

Yes No N/A

67. Was it especially difficult during adolescence to carry an EpiPen?

Yes No N/A- didn't carry one during adolescence N/A

68. **SCALE: Comfort** Scale: (1-very uncomfortable, 10- very comfortable) How embarrassing is it for you to use your EpiPen in a social setting? _____

69. If you chose to use Benedryl (antihistamine) instead of an epinephrine injection, was it because you felt it was more socially comfortable?

Yes No N/A

Information/Advice Received

The next section deals with what symptoms you may have been told to watch for in a reaction since some people are given advice on when to use medication, when to go to an emergency room or when to call 911. Not everyone has received this advice.

70. Have you been told or given any **information** by medical personnel, about allergy symptoms you need to be concerned about?

Yes No (skip to Q75) No, from a family member

71. If yes, **from whom** were you given the information:

ER Physician	Primary Care Physician
Allergist	Pharmacist
Nurse	Family member

72. In what way was the information about allergy symptoms to be concerned about conveyed to you?

Written instructions	Pamphlet
video	Verbal explanation
other _____	

73. Were you told a **medical term** used for a severe allergic reaction? (*if they don't know..., "we were wondering if you were told about the situation of anaphylaxis"*)

Yes No _____

74. **SCALE: Confidence** Scale: (1-helpless, 10-confident) Considering the information about allergy symptoms to be concerned about, can you tell me how confident or overwhelmed, you felt with this information? _____

Some people come up with what to do if they have another reaction by themselves, others have been counseled by a physician or other medical personnel very specifically as to what to do. We are interested if you have had this type of formal advice from medical personnel

75. Were you given an emergency **plan of action**? This would be a set of instructions telling you what to do and which medications to take if you have a reaction?

Yes No (skip to Q77)

76. **Who** gave you the plan of action?

ER Physician

Allergist

Nurse

Primary Care Physician

Pharmacist

Family member

77. Do you have any **suggestions** that could improve how you were informed or taught to take care of a severe reaction from medical personnel?

If you have been given a plan of action from medical personnel, I would like to know it what that plan is. If you have developed it on your own, that is great and I will put that down as well.

78. Can you **describe** to me what your (prescribed or self-developed) plan of action is?

80. **SCALE: Confidence** (1-helpless, 10-confident) Please rank how confident you feel about **using** your (prescribed or self-developed) plan of action? _____

81. **SCALE: Perception** (1-calm, 10-fearful) **If you were given a plan of action from medical personnel, (if not, skip to Q83)**
how comfortable did you feel receiving your plan of action information?_____
82. Have you ever had **conflicting plans** given to you by different physicians or other medical personnel? **Yes** **No**
Please explain any “yes” answer: _____

83. Have you ever used your prescribed plan of action while having a severe reaction?
 Yes **No**
84. **SCALE: Importance:** (1- not very important, 10- extremely important) How important do you think it is to have a plan of action?
85. **SCALE: Importance:** (1- not very important, 10- extremely important) How important do you think it is to have an emergency medication available in case of a severe reaction? _____
86. Do you have any ideas that you think could facilitate epinephrine use..... such as size, mechanism, improved education, etc.

Here, I am going to ask you questions about information you **HAVE BEEN GIVEN by medical personnel**, NOT information you looked up on your own through your own research.

87. Have you been given any information by medical personnel to help you understand food allergies and how and why your body reacts?

Yes No (skip to Q90)

88. If so, where did you receive it?

ER Physician

Primary Care Physician

Allergist

Pharmacist

Nurse

89. How were you given this information?

written

video

verbal

other _____

90. Were you given information about sources where **you, on your own**, could find out more information about food allergy (this could be in addition to information you were directly given)?

Yes No (skip to Q92)

91. What sources were you referred to?

Books

websites

support groups

other _____

92. Have you, **on your own, looked up** information to help you understand food allergy and how and why your body reacts?

Yes No (skip to Q95)

93. What sources did you use to find out more information about food allergy?

Books

websites

support groups

other _____

94. **SCALE: Confidence:** (1-helpless, 10- confident) If you have been given food allergy education information...***or did your own research and obtained information on your own (if neither applies, skip to Q96),***
How confident did you feel with this information? _____

95. **SCALE: Perception** (1-calm, 10-fearful) How comfortable did you feel receiving this information about your allergy? _____

96. **SCALE: Knowledge** (1-not informed, 10-very knowledgeable) How knowledgeable do you feel about understanding why your body reacts to certain foods?. _____

97. Do you think this information was helpful in motivating you to understand why it is important to avoid foods and have a plan of action to follow in case of a severe reaction?

Yes No N/A (Skip to Q100)

98. Do you use this information in your daily life?

Yes No N/A

99. What was the most helpful information you received? _____

Food Avoidance: Being able to avoid foods, reading labels on food products and understanding cross contamination are important tools which will decrease your chance of having a severe reaction. *Some people have received extensive information on avoiding foods, others have not been told anything by medical personnel and did their own research or have learned by long experience. We are interested here in what you were advised by medical personnel, if anything at all.*

100. **Advice from Medical Personnel ONLY:** Were you told to avoid foods you were allergic to?

Yes No No, Family member

101. **Advice from Medical Personnel ONLY** Were you taught how to avoid the foods?

Yes No No, Family member

102. **Advice from Medical Personnel ONLY:** Were you taught how to read labels on food packages:

Yes No No, Family member

103. **Advice from Medical Personnel ONLY: Interviewer:** Show the Food allergy & Anaphylaxis Network list (*Use list specific to subject's particular allergy: milk, tree nuts, peanuts, shrimp*)

Were you shown this kind of list? **Yes No**

Now I am going to ask some general questions about issues in food allergy that you may or may not have heard of – whether on your own or from medical personnel. We are interested in whether any of the following are relevant to you.

104. Have you heard of the problem of cross-contamination?

Yes No

Read this explanation after the yes/no answer: *This is a situation where a food may contain an allergen because of accidental contact with the allergen – like a knife used to spread peanut butter being wiped off and then used to cut birthday cake, or stir fried food being made in a wok that was just used for cashew chicken, or grilling a steak on a barbecue that had shrimp kabobs. (use an example with the food they are allergic to)*

105. Have you ever had a reaction due to cross-contamination of foods?

Yes No

106. Do you go out to eat in restaurants?

Yes No

107. Have you heard about how to avoid allergenic foods in Restaurants?

Yes No (skip to Q109)

108. How did you hear about this?:

Medical Personnel

Self-taught

Family Member

109. **SCALE: Comfort:** (1-not at all comfortable to 10-very comfortable), How comfortable do you feel discussing your food allergy needs with waiters and other food service workers in a Restaurant? _____

110. Have you had a reaction in a Restaurant?

Yes No

111. Have you heard that you can have a reaction by: kissing or breathing in particles?

Yes No (skip to Q113)

112. How did you hear about this?

Medical Personnel

Self-taught

Family Member

113. Have you had a reaction by kissing?

Yes No

114. Have you had a reaction by Breathing cooking vapors?

Yes No

115. Have you had a reaction by breathing in particles, such as on an airplane s?

Yes No

116. **SCALE: Confidence:** (1-helpless, 10-confident), If you received education, how helpless or confident did you feel after being educated on how you could avoid foods and situations where foods could give you a reaction? _____ **N/A**

117. **SCALE: Knowledge Scale-** On a scale of (1-not very informed, 10-very knowledgeable) If you received education, how informed, or knowledgeable do you feel about being able to avoid foods? _____ **N/A**

118. **SCALE: Confidence** (1-helpless, 10 very confident) How confident do you feel that you can avoid having a severe reaction by carefully avoiding foods **at home**?

119. **SCALE: Confidence** (1-helpless, 10 very confident) How confident do you feel that you can avoid having a severe reaction by carefully avoiding foods **away from home**? _____

120. Do you have any ideas that could improve how food avoidance is being taught or explained? _____

Some people have said that they had a lot of support for family and friends in avoiding the food they were allergic to, others have said that they were given a hard time. We would like to know how it has been for you.

121. At the time you first developed food allergy, were you living with your:

- Parents
- Friend(s)
- Spouse

122. Skip this question if they were a small child at the time: Depending on your living situation at the time of your reaction(s), did you feel comfortable explaining your need to avoid foods and your emergency plan of action, *if you had one, to the following people:*

- | | | | |
|------------------|------------|-----------|------------|
| a) Parents | Yes | No | |
| b) Friends | Yes | No | |
| c) Spouse | Yes | No | N/A |
| N/A, small child | | | |

123. NOW do you feel comfortable explaining your need to avoid foods and your emergency plan of action, if you have one, to the following people?

- | | | | |
|--------------|------------|-----------|------------|
| a) Parents | Yes | No | |
| b) Friends | Yes | No | |
| c) Spouse | Yes | No | N/A |
| d) Strangers | Yes | No | |

124. Did they/do they support you by changing the food habits in your home *or when they were around you?*

- | | | | |
|------------|------------|-----------|------------|
| a) Parents | Yes | No | |
| b) Friends | Yes | No | |
| c) Spouse | Yes | No | N/A |

125. **SCALE: Importance** (1-not important, 10- very important) How important do you feel it is to have the support of people closest to you in regards to your allergy?

126. Do you think there is any information or process medical personnel could give you that could help you in receiving more support from your family and friends?

127. **SCALE: Comfort:** On a scale of (1-not at all comfortable to 10-very comfortable), How comfortable do you feel discussing your food allergy with your Primary Care Physician or Allergist and bringing up concerns you may have?

128. Will your insurance company cover a prescription for an EpiPen?

Yes No Don't know

129. Will your insurance company cover an allergist referral?

Yes No Don't know

130. Other- do you have religious reasons for not wanting to use an EpiPen or other medication?

Yes No N/A

Appendix

I. SCALES

- 1) Perception Scale: 1- calm, 10- fearful
- 2) Severity of Reaction Scale: 1-very mild, not life threatening, 10- very severe, life threatening
- 3) Confidence Scale: 1- helpless, 10- confident
- 4) Knowledge Information Scale: 1- not very informed, 10- highly knowledgeable
- 5) Importance Scale: 1- not very important, 10- very important
- 6) Comfort Scale: 1-very uncomfortable, 10- very comfortable

II Food Allergen Ingredients Lists (FAAN Label Reading) (to show subjects on label question).

APPENDIX D
ORAL QUESTIONNAIRE INTERVIEW MATERIALS

Scale Reference Sheet

1. **Perception:**
1 – calm, 10 – fearful
2. **Severity of Reaction:**
1 – very mild, not life threatening, 10 – very severe, life threatening
3. **Confidence:**
1 – helpless, 10 – confident
4. **Knowledge:**
1 – not very informed, 10 – highly knowledgeable
5. **Importance:**
1 – not very important, 10 – very important
6. **Comfort:**
1 – very uncomfortable, 10 – very comfortable

HOW TO READ A LABEL for a MILK-FREE DIET <i>Avoid foods that contain milk or any of these ingredients:</i>	
artificial butter flavor butter, butter fat, butter oil buttermilk casein (<i>casein hydrolysate</i>) caseinates (<i>in all forms</i>) cheese cream cottage cheese curds custard ghee half & half lactalbumin, lactalbumin phosphate lactoferrin lactulose milk (<i>in all forms including condensed, derivative, dry, evaporated, goat's milk and milk from other animals, low-fat, malted, milkfat, non-fat, powder, protein, skimmed, solids, whole</i>)	nisin nougat pudding recaldent rennet casein sour cream, sour cream solids sour milk solids whey (<i>in all forms</i>) yogurt <i>May indicate the presence of milk protein:</i> caramel candies chocolate flavorings (<i>including natural and artificial</i>) high protein flour lactic acid starter culture lactose luncheon meat, hot dogs, sausages margarine non-dairy products



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HOW TO READ A LABEL for an EGG-FREE DIET <i>Avoid foods that contain eggs or any of these ingredients:</i>	
albumin (<i>also spelled as albumen</i>) egg (<i>dried, powdered, solids, white, yolk</i>) eggnog lysozyme mayonnaise meringue (<i>meringue powder</i>) surimi	<i>May indicate the presence of egg protein:</i> flavoring (<i>including natural and artificial</i>) lecithin macaroni marzipan marshmallows nougat pasta

HOW TO READ A LABEL for a PEANUT-FREE DIET <i>Avoid foods that contain peanuts or any of these ingredients:</i>	
artificial nuts beer nuts cold pressed, expelled, or extruded peanut oil goobers ground nuts mixed nuts monkey nuts nutmeat nut pieces peanut peanut butter peanut flour	<i>May indicate the presence of peanut protein:</i> African, Asian (<i>especially Chinese, Indian, Indonesian, Thai, and Vietnamese</i>), and Mexican dishes baked goods (<i>pastries, cookies, etc.</i>) candy (<i>including chocolate candy</i>) chili egg rolls enchilada sauce flavoring (<i>including natural and artificial</i>) marzipan mole sauce nougat <ul style="list-style-type: none"> • Mandelonas are peanuts soaked in almond flavoring. • Studies show most allergic individuals can safely eat peanut oil (<i>not</i> cold pressed, expelled, or extruded peanut oil). • Arachis oil is peanut oil. • Experts advise patients allergic to peanuts to avoid tree nuts as well. • A study showed that unlike other legumes, there is a strong possibility of cross reaction between peanuts and lupine. • Sunflower seeds are often produced on equipment shared with peanuts.

HOW TO READ A LABEL for a WHEAT-FREE DIET <i>Avoid foods that contain wheat or any of these ingredients:</i>	matzoh, matzoh meal (<i>also spelled as matzo</i>)
bran	pasta
bread crumbs	seitan
bulgur	semolina
club wheat	spelt
couscous	triticale
cracker meal	vital gluten
durum	wheat (<i>bran, germ, gluten, malt, sprouts</i>)
einkorn	wheat grass
emmer	whole wheat berries
farina	<i>May indicate the presence of wheat protein:</i>
flour (<i>all purpose, bread, cake, durum, enriched, graham, high gluten, high protein, instant, pastry, self-rising, soft wheat, steel ground, stone ground, whole wheat</i>)	flavoring (<i>including natural and artificial</i>)
gluten	hydrolyzed protein
kamut	soy sauce
	starch (<i>gelatinized starch, modified starch, modified food starch, vegetable starch, wheat starch</i>)
	surimi

HOW TO READ A LABEL for a SOY-FREE DIET <i>Avoid foods that contain soy or any of these ingredients:</i>	<i>May indicate the presence of soy protein:</i>
edamame	Asian cuisine
hydrolyzed soy protein	flavoring (<i>including natural and artificial</i>)
miso	vegetable broth
natto	vegetable gum
soy sauce	vegetable starch
soy (<i>soy albumin, soy fiber, soy flour, soy grits, soy milk, soy nuts, soy sprouts</i>)	<ul style="list-style-type: none"> Studies show most individuals allergic to soy may safely eat soybean oil. Most individuals allergic to soy can safely eat soy lecithin.
soya	Check with your doctor if you have questions about these ingredients.
soybean (<i>curd, granules</i>)	
soy protein (<i>concentrate, isolate</i>)	
soy sauce	
Tamari	
Tempeh	
textured vegetable protein (<i>TVP</i>)	
tofu	

HOW TO READ A LABEL for a SHELLFISH-FREE DIET <i>Avoid foods that contain shellfish or any of these ingredients:</i>	
abalone	
clams (<i>cherrystone, littleneck, pismo, quahog</i>)	
cockle (<i>periwinkle, sea urchin</i>)	
crab	
crawfish (<i>crayfish, ecrevisse</i>)	
lobster (<i>langouste, langoustine, scampo, coral, tomalley</i>)	
mollusks	
mussels	
octopus	
oysters	
prawns	
scallops	
shrimp (<i>crevette</i>)	
snails (<i>escargot</i>)	
squid (<i>calamari</i>)	
<i>May indicate the presence of shellfish protein:</i>	
bouillabaisse	
cuttlefish ink	
fish stock	
flavoring (<i>including natural and artificial</i>)	
seafood flavoring (<i>such as crab or clam extract</i>)	
surimi	
<i>Keep the following in mind:</i>	
<ul style="list-style-type: none"> Any food served in a seafood restaurant may be cross contaminated with fish or shellfish. For some individuals, a reaction may occur from cooking odors or from handling fish or shellfish. Always carry medications and use them as soon as symptoms develop. 	

HOW TO READ A LABEL for a TREE NUT-FREE DIET <i>Avoid foods that contain nuts or any of these ingredients:</i>	nougat
almonds	nut butters (<i>i.e., cashew butter</i>)
artificial nuts	nut meal
beech nut	nutmeat
Brazil nuts	nut oil
butternut	nut paste (<i>i.e., almond paste</i>)
caponata	nut pieces pecans (<i>Mashuga Nuts®</i>)
cashews	pesto
chestnuts	pili nut
chin quapin	pine nuts (<i>also referred to as Indian, piñon, pinyon, pignoli, pignolia, and pignon nuts</i>)
coconut	pistachios
filberts/hazelnuts	praline
gianduja (<i>a nut mixture found in some chocolate</i>)	sheanut
ginko nut	walnuts
hickory nuts	<ul style="list-style-type: none"> Mandelonas are peanuts soaked in almond flavoring. Mortadella may contain pistachios. Natural and artificial flavoring may contain tree nuts. Experts advise patients allergic to tree nuts avoid peanuts as well. Talk to your doctor if you find other nuts not listed here.
lichee/lychee nut	
macadamia nuts	
marzipan/almond paste	
nan-gai nuts	
natural nut extract (<i>i.e., almond, walnut</i>)	

REFERENCES

- Adshead A. 2006. Food without fear. *Caterer & Hotelkeeper* 196(4438):28.
- Food Allergy Statistics [Internet]; c2008a [cited 2008 March 25]. Available from: <http://www.aaaai.org/patients/gallery/foodallergy.asp?item=1a>.
- Allergic Conditions: Epinephrine [Internet]; c2008b [cited 2008 March 25]. Available from: http://www.aaaai.org/patients/allergic_conditions/epinephrine.stm.
- Tips to Remember: Food allergy [Internet]; c2007a [cited 2008 March 25]. Available from: <http://www.aaaai.org/patients/publicedmat/tips/foodallergy.stm>.
- Tips to Remember: What is an allergic reaction? [Internet]; c2007b [cited 2008 March 25]. Available from: <http://www.aaaai.org/patients/publicedmat/tips/whatisallergicreaction.stm>.
- Tips to Remember: What is anaphylaxis? [Internet]; c2007c [cited 2008 March 25]. Available from: <http://www.aaaai.org/patients/publicedmat/tips/whatisanaphylaxis.stm>.
- Andrews T and Banks JR. 2005. Prevalence of peanut and tree nut allergy in the United States determined by means of a random digit dial telephone survey: A 5-year follow-up study. *Pediatrics* 116(2):544-5.
- Arkwright PD and Farragher AJ. 2006. Factors determining the ability of parents to effectively administer intramuscular adrenaline to food allergic children. *Pediatric Allergy and Immunology* 17(3):227-9.
- Barth S. 2004. How to prevent food and beverage liability. *Lodging Hospitality* 60(7):36-8.
- Bender BG. 2002. Overcoming barriers to nonadherence in asthma treatment. *Journal of Allergy and Clinical Immunology* 109(6, Part 2):554-9.
- Bren L. 2006. Food labels identify allergens more clearly. *FDA Consumer* 40(2):37-8.
- Buchanan AD, Green TD, Jones SM, Scurlock AM, Christie L, Althage KA, Steele PH, Pons L, Helm RM, Lee LA, et al. 2007. Egg oral immunotherapy in nonanaphylactic children with egg allergy. *Journal of Allergy and Clinical Immunology* 119(1):199-205.

Clark S and Camargo CAJ. 2005. Emergency management of food allergy: Systems perspective. *Current Opinion in Allergy & Clinical Immunology* 5(3):293-8.

Cohen BL, Noone S, Munoz-Furlong A, Sicherer SH. 2004. Development of a questionnaire to measure quality of life in families with a child with food allergy. *Journal of Allergy and Clinical Immunology* 114(5):1159-63.

About EpiPen [Internet]; c2008 [cited 2008 April 30]. Available from: http://www.epipen.com/epipen_main.aspx.

Duecy E. 2004. Food allergies nothing to sneeze at, chains say. *Nation's Restaurant News* 38(38):143.

Ewan PW and Clark AT. 2005. Efficacy of a management plan based on severity assessment in longitudinal and case-controlled studies of 747 children with nut allergy: Proposal for good practice. *Clinical & Experimental Allergy* 35(6):751-6.

Anaphylaxis [Internet]; c2006a [cited 2008 March 25]. Available from: <http://www.foodallergy.org/anaphylaxis/index.html>.

Food Allergy Facts and Statistics [Internet]; c2008 [cited 2008 March 14]. Available from: <http://www.foodallergy.org/downloads/FoodAllergyBasics.pdf>.

Frequently Asked Questions [Internet]; c2006b [cited 2008 March 25]. Available from: <http://www.foodallergy.org/questions.html>.

Formanek Jr R. 2001. Food allergies when food becomes the enemy. *FDA Consumer* 35(4):10.

Furlong TJ, DeSimone J, Sicherer SH. 2001. Peanut and tree nut allergic reactions in restaurants and other food establishments. *Journal of Allergy and Clinical Immunology* 108(5):867-70.

Gold MS and Sainsbury R. 2000. First aid anaphylaxis management in children who were prescribed an epinephrine autoinjector device (EpiPen). *Journal of Allergy and Clinical Immunology* 106(1):171-6.

Harmer J. 2005. The danger list. *Caterer & Hotelkeeper* 194(4375):32-6.

Joshi P, Mofidi S, Sicherer SH. 2002. Interpretation of commercial food ingredient labels by parents of food-allergic children. *Journal of Allergy and Clinical Immunology* 109(6):1019-21.

Kagan RS. 2003. Food allergy: An overview. *Environmental Health Perspectives* 111(2):223-5.

Kalb, C. 2007. Fear and allergies in the lunchroom. *Newsweek* 150(19): 42-47.

Kapoor S, Roberts G, Bynoe Y, Gaughan M, Habibi P, Lack G. 2004. Influence of a multidisciplinary paediatric allergy clinic on parental knowledge and rate of subsequent allergic reactions. *Allergy* 59(2):185-91.

Kim JS, Sinacore JM, Pongracic JA. 2005. Parental use of EpiPen for children with food allergies. *Journal of Allergy and Clinical Immunology* 116(1):164-8.

Kukkonen K, Savilahti E, Haahtela T, Juntunen-Backman K, Korpela R, Poussa T, Tuure T, Kuitunen M. 2007. Probiotics and prebiotic galacto-oligosaccharides in the prevention of allergic diseases: A randomized, double-blind, placebo-controlled trial. *Journal of Allergy and Clinical Immunology* 119(1):192-8.

Food Allergy Buddy [Internet]; c2007 [cited 2008 March 25]. Available from: <http://www.foodallergybuddy.com>.

Mandabach, K.H., Bloomquist, P., Rande, W., & VanLeeuwen, D. 2002. Food allergies in hospitality management curricula: One bite can be deadly. *Journal of Hospitality & Tourism Education* 14: 33-39.

Mandabach, K.H., Ellsworth, A., VanLeeuwen, D.M., Blanch, G., & Waters, H.L. 2005. Restaurant managers' knowledge of food allergies: A comparison of differences by chain or independent affiliation, type of service and size. *Journal of Culinary Science & Technology* 4(2/3): 63-77.

Miles S, Fordham R, Mills C, Valovirta E, Mugford M. 2005. A framework for measuring costs to society of IgE-mediated food allergy. *Allergy* 60(8):996-1003.

Modlin M and Krummert B. 2005. How to reduce risk in your restaurant. *Restaurant Hospitality* 89(7):28.

Morgan-Harris J. 2004. Food allergies. *Caterer & Hotelkeeper* 193(4355):45-.

Phillipo, L. 2007. The Impact of Education on the Consumer's Ability to Manage Life-Threatening Food Allergies. MS Thesis, University of California, Davis.

Romeo P. 2003. Breathtaking. *Restaurant Business* 102(2):4.

Sampson HA. 2004. Update on food allergy. *Journal of Allergy and Clinical Immunology* 113(5):805-19.

- Sampson HA. 1999a. Food allergy. Part 1: Immunopathogenesis and clinical disorders. *Journal of Allergy and Clinical Immunology* 103(5):717-28.
- Sampson HA. 1999b. Food allergy. Part 2: Diagnosis and management. *Journal of Allergy and Clinical Immunology* 103(6):981-9.
- Sampson MA, Munoz-Furlong A, Sicherer SH. 2006. Risk-taking and coping strategies of adolescents and young adults with food allergy. *Journal of Allergy and Clinical Immunology* 117(6):1440-5.
- Sicherer SH. 2000. Determinants of systemic manifestations of food allergy. *Journal of Allergy and Clinical Immunology* 106(5, Part 2):251-7.
- Sicherer SH and Sampson HA. 2006. Food allergy. *Journal of Allergy and Clinical Immunology* 117(2, Supplement 2):S470-5.
- Sicherer SH, Teuber S. 2004. Current approach to the diagnosis and management of adverse reactions to foods. *Journal of Allergy and Clinical Immunology* 114(5):1146-50.
- Sicherer SH, Munoz-Furlong A, Sampson HA. 2004. Prevalence of seafood allergy in the United States determined by a random telephone survey. *Journal of Allergy and Clinical Immunology* 114(1):159-65.
- Simons FER. 2004. First-aid treatment of anaphylaxis to food: Focus on epinephrine. *Journal of Allergy and Clinical Immunology* 113(5):837-44.
- Simons FER, Gu X, Simons KJ. 2000. Outdated EpiPen and EpiPen Jr autoinjectors: Past their prime? *Journal of Allergy and Clinical Immunology* 105(5):1025-30.
- Simonte SJ, Ma S, Mofidi S, Sicherer SH. 2003. Relevance of casual contact with peanut butter in children with peanut allergy. *Journal of Allergy and Clinical Immunology* 112(1):180-2.
- Taylor, SL and Hefle, SL. 2001. Food allergies and other food sensitivities. *Food Technology* 55(9):68-83.
- Taylor SL and Hefle SL. 2006. Food allergen labeling in the USA and Europe. *Current Opinion in Allergy & Clinical Immunology* 6(3):186-190.
- Tellem S. 2005. Food safety checks & balances. *Restaurant Hospitality* 89(1):80-1.

United States Food and Drug Administration. 2006. Food allergen labeling and consumer protection act of 2004. 108-282:201-10.

United States Food and Drug Administration, Center for Food Safety and Applied Nutrition. 2006. Approaches to establish thresholds for major food allergens and for gluten in food. Available from: <http://www.cfsan.fda.gov/~dms/alrgn2.html>.

van Putten MC, Frewer LJ, Gilissen LJWJ, Gremmen B, Peijnenburg AACM, Wichers HJ. 2006. Novel foods and food allergies: A review of the issues. *Trends in Food Science & Technology* 17(6):289-99.

Learn more about Twinject [Internet]; c2008 [cited 2008 April 30]. Available from: http://www.twinject.com/patients/learn_more.html.

Wang J and Sampson HA. 2007. Food anaphylaxis. *Clinical & Experimental Allergy* 37(5):651-60.

Zeiger RS and Schatz M. 2000. Effect of allergist intervention on patient-centered and societal outcomes: Allergists as leaders, innovators, and educators. *Journal of Allergy and Clinical Immunology* 106(6):995-1018.